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UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

DISPUTE SETTLEMENT

WORLD TRADE ORGANIZATION

3.9 SPS Measures



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NOTE

The Course on Dispute Settlement in International Trade, Investment and Intellectual Property consists of forty modules.

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WHAT YOU WILL LEARN

The *Agreement on the Application of Sanitary and Phytosanitary Measures*, commonly referred to as the *SPS Agreement*, is one of the WTO agreements which resulted from the Uruguay Round of Multilateral Trade Negotiations, held from 1986 to 1993 under the auspices of the GATT. The *SPS Agreement* is contained in Annex 1 A of the 1994 *Marrakesh Agreement Establishing the World Trade Organization* and came into force on 1 January 1995. This Agreement was negotiated in tandem with the *Agreement on Agriculture*, as negotiators wanted to ensure that the hard-won liberalization in the agricultural sector achieved by the *Agreement on Agriculture* would not be undermined by the misuse of health regulations for protectionist purposes. Thus, the *SPS Agreement* creates disciplines applicable to measures for the protection of human and animal life or health (sanitary measures) and of plant life or health (phytosanitary measures) from certain, defined risks. It aims to balance the right of Members to take measures to protect health in their territories from risks contained in traded food and agricultural products, with the goal of trade liberalization in the food and agricultural sector. Generally speaking, the *SPS Agreement* thus aims to reconcile free trade with legitimate concerns for the life and health of humans, animals and plants. The *SPS Agreement* is of particular importance for developing countries, many of whom are primary agricultural exporters and depend on access to foreign markets for their agricultural products for much of their foreign revenue.

This Module provides an overview of the substantive and procedural disciplines contained in the *SPS Agreement*, and sets out the jurisprudence of the panels and Appellate Body of the WTO in respect of this Agreement. It also pays particular attention to the position of developing countries under the *SPS Agreement*.

The first Section of this Module deals with the scope of application of the *SPS Agreement* and describes its relationship to other relevant WTO agreements. This will enable the trainee to identify when the *SPS Agreement* is applicable to a particular factual situation. The second Section lays out the basic principles of the *SPS Agreement*, namely the right of Members to take SPS measures and the basic disciplines surrounding the exercise of this right, as well as the underlying goal of harmonization of SPS measures. The third examines the risk analysis obligations that Members must comply with when imposing SPS measures. This section encompasses both risk assessment obligations and risk management disciplines and devotes some attention to the use of provisional measures in cases of scientific uncertainty. The fourth Section deals with the remaining substantive provisions of the *SPS Agreement*, namely the rules on the recognition of equivalence and adaptation to regional conditions. The fifth is devoted to the institutional and procedural rules contained in the *SPS Agreement*, including those on the role of the SPS Committee and those governing dispute settlement under the *SPS Agreement*, to the extent that these differ from the general dispute settlement rules addressed in Modules

3.1 to 3.4. The sixth Section specifically addresses the special provisions for developing countries in the *SPS Agreement*. This Module concludes with a set of hypothetical case studies, designed to test the reader's knowledge and illustrate the practical application of the theory learnt. Finally, some recommendations are made for further reading.

1. SCOPE OF APPLICATION OF THE SPS AGREEMENT

On completion of this section the reader will be able:

- to identify the circumstances in which the *Agreement on the Application of Sanitary and Phytosanitary Measures*, or the *SPS Agreement*, applies to a factual situation.
- to explain what is meant by a “sanitary or phytosanitary measure” under this Agreement and be able to determine whether the Agreement applies to a particular dispute.
- to understand the relationship between the *SPS Agreement* and other WTO Agreements relevant in this area.

1.1 Substantive Scope of Application

Article 1.1 SPS

Article 1.1 of the *SPS Agreement* defines the scope of application of the Agreement. It provides:

This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.

Thus, as stated by the Panel in *EC - Hormones*, there are two requirements for the *SPS Agreement* to apply, namely that the measure in dispute is an SPS measure and that the measure, directly or indirectly, affects international trade.¹

1.1.1 Definition of an SPS Measure

Article 1.2 and Annex A.1 SPS

Not all measures aimed at public health protection are SPS measures for purposes of the *SPS Agreement*. Article 1.2 points to Annex A of the *SPS Agreement* for the definitions of the terms used in the Agreement. Paragraph 1 of Annex A, defines SPS measures as follows:

Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;



¹ Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones)* (“EC – Hormones (US)”), complaint by the United States, WT/DS26/R/USA, DSR 1998:III, 699, para. 8.38; and Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones)* (“EC – Hormones (Canada)”), by Canada, WT/DS48/R/CAN, DSR 1998:II, 235, para. 8.39.

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests. Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

It is clear from the above definition that the question whether a measure falls there under depends on its *purpose or goal*. Broadly speaking, the definition covers measures aimed at protecting humans and animals from food-borne health risks and protecting humans, animals and plants from risks from pests or diseases. Measures addressing other health risks relevant for international trade (such as a ban on asbestos-containing products) and measures not directly aimed at health protection, but rather at consumer information (such as a labelling requirement for biologically grown vegetables), do not fall under this definition. Such measures would thus not be subject to the disciplines of the *SPS Agreement* but be dealt with under other WTO rules.

While this has not yet been subject to dispute settlement, it would appear that the *purpose or goal* of a measure would be determined objectively (for example by examining the formulation of the measure, its structure or design, and its effect), rather than by trying to determine the subjective aim of the Member imposing it. The latter would have the clearly unintended result of enabling a Member to evade the disciplines of the *SPS Agreement* by denying that the purpose of its measure is one of those falling within the Annex A.1 definition.

If the measure at issue is aimed at one of the goals mentioned in points (a) to (d) of the Annex A.1 definition, it is an SPS measure for the purposes of the *SPS Agreement*, regardless of the specific form it takes. This appears from the second part of the definition, which contains a broad, illustrative, non-exhaustive list of various types of government measures which could be classified as SPS measures, ranging from end-product criteria and quarantine requirements to certification and sampling procedures.

It is important to note that the Annex A.1 definition expressly refers to the protection of human, plant or animal life or health *within the territory of the Member*. Thus, measures aiming at the extra-territorial application of domestic health standards are excluded from the application of the *SPS Agreement*.

1.1.2 Discriminatory and Non-discriminatory Measures

The scope of application of the *SPS Agreement* is not limited to discriminatory SPS measures. When negotiating the *SPS Agreement*, Members realized that a test based on discrimination is not sufficient to separate legitimate SPS measures from those used for protectionist purposes. It is possible for a measure that neither on its face nor in practice discriminates between domestic and imported products to have a negative impact on international trade and thus serve to protect the domestic producers from foreign competition. For this reason, the disciplines of the *SPS Agreement* catch both discriminatory and non-discriminatory SPS measures that affect international trade. It is therefore possible for a measure that is non-discriminatory and thus in conformity with the GATT 1994, to violate the *SPS Agreement*.

1.1.3 Effect on International Trade

Article 1.1 SPS

The second requirement laid down in Article 1.1 for the application of the *SPS Agreement* is that the measure at issue must directly or indirectly affect international trade. Empirical proof of a reduction in trade flows is not required, but it suffices to show that the measure is applied to imports and therefore can be presumed to have an impact on international trade. The requirement of an effect on international trade should thus be easy to fulfil and has in fact not been in dispute in any SPS case thus far.

1.2 Temporal Scope of Application

The *SPS Agreement* came into force on 1 January 1995. The question thus arises whether SPS measures in existence before this date are subject to its provisions. In *EC - Hormones* the EC argued that as its ban on hormone-treated beef predated the entry into force of the *SPS Agreement*, this ban was not subject to the disciplines of the *SPS Agreement*. Upholding the Panel's finding rejecting this argument, the Appellate Body held:

If the negotiators had wanted to exempt the very large group of SPS measures in existence on 1 January 1995 from the disciplines of provisions as important as Articles 5.1 and 5.5, it appears reasonable to us to expect that they would have said so explicitly. Articles 5.1 and 5.5 do not distinguish between SPS measures adopted before 1 January 1995 and measures adopted since; the relevant implication is that they are intended to be applicable to both.²

Furthermore the Appellate Body pointed to Article XVI:4 of the *WTO Agreement* which obliges Members to ensure the conformity of their laws, regulations and procedures with their obligations under the annexed

² Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)* ("EC – Hormones"), WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:I, 135, para. 128.

Agreements.³ It is thus apparent that Members have to review their existing SPS measures in the light of the new disciplines of the *SPS Agreement*.

1.3 Application to Bodies Other than Central Government

Article 13 SPS

The disciplines contained in the *SPS Agreement* are not only applicable to measures by central governments. According to Article 13 of the *SPS Agreement*, Members are fully responsible for the observance of the *SPS Agreement* and are obliged to take positive measures to ensure the compliance with its provisions by other than central government bodies. In addition, Members must take reasonable measures to ensure that non-governmental bodies in their territories and regional bodies, in which relevant entities in their territories are members, comply with the rules of the *SPS Agreement*. Members may only rely on the services of non-governmental bodies for the implementation of SPS measures if these bodies comply with the provisions of the *SPS Agreement*. Further, Members may not require or encourage regional, non-governmental or local government bodies to act in a way contrary to the Agreement.⁴

1.4 Relationship with Other WTO Agreements

1.4.1 TBT Agreement

Article 1.4 SPS and Article 1.5 TBT

During the Tokyo Round trade negotiations, the first steps were taken towards addressing the problem of non-tariff barriers to trade, in the form of technical regulations, by the conclusion of the *Agreement on Technical Barriers to Trade*, commonly known as the *Standards Code*. This agreement was not very effective and was, as a result of the Uruguay Round negotiations, replaced by the new *WTO Agreement on Technical Barriers to Trade* (the *TBT Agreement*) which tightens the disciplines of the *Standards Code*. The *TBT Agreement* is broadly applicable to technical regulations and standards, including those aimed at the protection of health. However, in the Uruguay Round negotiations, negotiators saw SPS measures as meriting special rules, apart from those applicable to the broader category of technical regulations and standards. Thus a separate Agreement, the *SPS Agreement* was concluded to deal specifically with SPS measures.

The importance of determining which of these two agreements applies to a particular measure lies in the fact that their respective rules differ, those of the *TBT Agreement* being less strict than those of the *SPS Agreement*. In order to establish which of the two Agreements applies to a particular measure, recourse must be had to Article 1.5 of the *TBT Agreement* which states:

³ *Ibid.*

⁴ This provision was applied in *Compliance Panel Report, Australia – Measures Affecting Importation of Salmon - Recourse to Article 21.5 of the DSU by Canada*, (“*Australian – Salmon*”), WT/DS18/RW para. 7.13, with respect to a measure by the provincial government of Tasmania.

The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in the Agreement on the Application of Sanitary and Phytosanitary Measures.

In addition, Article 1.4 of the *SPS Agreement* provides that nothing in that Agreement shall affect the rights of Members under the *TBT Agreement* with regard to measures not falling within the scope of the *SPS Agreement*. Clearly, therefore, the *SPS Agreement* and the *TBT Agreement* are mutually exclusive.

Once a measure falls within the definition of an SPS measure in the *SPS Agreement*, it is subject to the rules of this Agreement to the exclusion of the *TBT Agreement*, even if the measure is also a technical regulation or standard within the meaning of the *TBT Agreement*. On the other hand, if a measure qualifies as a technical regulation or standard and is *not* an SPS measure, the *TBT Agreement* applies.

The first step in determining the applicable agreement will therefore always be to establish whether the measure at issue is an SPS measure. If so, it is no longer necessary to examine whether it is a technical regulation or standard for purposes of the *TBT Agreement* as the measure falls outside its scope of application.

1.4.2 GATT 1994

Article XX(b) GATT

The *General Agreement on Tariffs and Trade* (the GATT), unlike the *SPS Agreement* and the *TBT Agreement*, does not only apply to a circumscribed category of measures, but covers all measures relating to trade in goods. In this sense, it is broader in its application than the *SPS Agreement*, which applies only to SPS measures. On the other hand, only health measures that are discriminatory will be GATT-inconsistent and fall to be examined under Article XX(b) of the GATT, whereas the *SPS Agreement* catches all SPS measures, whether they are discriminatory or non-discriminatory. In this sense, the GATT is narrower in its application than the *SPS Agreement*.

Before the entry into force of the *SPS Agreement*, Members could impose and maintain GATT-inconsistent measures necessary for the protection of human, animal and plant life or health under the exception provided in Article XX(b) of the GATT 1947. The inadequacy of this provision in dealing with the complexities of SPS measures, led Members to negotiate the *SPS Agreement* in the Uruguay Round, in an attempt to flesh out Article XX(b) and set clear limits to the use of SPS measures in ways that could adversely affect international trade. However, the resultant *SPS Agreement* goes further than a mere elaboration of Article XX(b) of the GATT, and establishes a new, comprehensive set of norms for the adoption and maintenance of SPS measures.

The question arises whether, as is the case with Article XX(b), a violation of the GATT must be shown before the *SPS Agreement* can be applicable. This

question arose in *EC - Hormones* and the Panel in that case found that the only two requirements for the applicability of the *SPS Agreement* are those contained in Article 1.1, namely the existence of an SPS measure and a direct or indirect effect on international trade and that there is no further express requirement of a violation of the GATT.⁵ In addition, the Panel went on to state:

Moreover, we find the EC claim that the SPS Agreement does not impose “substantive” obligations additional to those already contained in Article XX(b) of GATT not to be persuasive. It is clear that some provisions of the SPS Agreement elaborate on provisions already contained in GATT, in particular Article XX(b). The final preambular paragraph of the SPS Agreement provides, indeed, that the Members desired “to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)”. Examples of such rules are, arguably, some of the obligations contained in Article 2 of the SPS Agreement. However, on this basis alone we cannot conclude that the SPS Agreement only applies, as Article XX(b) of GATT does, if, and only if, a prior violation of a GATT provision has been established. Many provisions of the SPS Agreement impose “substantive” obligations which go significantly beyond and are additional to the requirements for invocation of Article XX(b). These obligations are, inter alia, imposed to “further the use of harmonized sanitary and phytosanitary measures between Members” and to “improve the human health, animal health and phytosanitary situation in all Members”. They are not imposed, as is the case of the obligations imposed by Article XX(b) of GATT, to justify a violation of another GATT obligation (such as a violation of the non-discrimination obligations of Articles I or III).⁶

**Interpretative Note to
Annex 1A and Article
2.4 SPS**

The *SPS Agreement* did not, however replace the provisions of the GATT 1947 (now incorporated by reference into the GATT 1994), relevant to health measures. Nor is the *SPS Agreement* subordinate to the GATT. Instead the two Agreements now operate in complement to each other, and to the *TBT Agreement*. Where a measure for the protection of health is at issue, it could therefore be caught by any of the three Agreements depending on the nature and content of the measure. The current position of health measures is consequently determined by the disciplines of these three Agreements within their respective spheres of application.

Unlike the situation with the *TBT Agreement*, there is no provision making the *SPS Agreement* and the GATT mutually exclusive. Thus a measure which falls within the definition of an SPS measure may also be subject to GATT rules.

The relationship between the GATT 1994 and the other Annex 1A Agreements (i.e. those agreements dealing with trade in goods), one of which is the *SPS Agreement*, is governed by the *Interpretative Note to Annex 1A*. The

⁵ Panel Report, *EC – Hormones (US)*, para. 8.36 and Panel Report, *EC – Hormones (Canada)*, para. 8.39.

⁶ Panel Report, *EC - Hormones (US)* para. 8.38 and 8.40.

Interpretative Note provides that in the event of a conflict between a provision of the GATT 1994 and a provision in another Annex 1A Agreement, the latter prevails to the extent of the conflict. Thus the provisions of the *SPS Agreement* would have precedence over any conflicting GATT rule.

However the likelihood that there would be a conflict between the relevant GATT rules and the disciplines of the *SPS Agreement* is negligible, as the *SPS Agreement* takes on board the GATT disciplines relevant to health measures and elaborates on them. This fact is recognized in Article 2.4 of the *SPS Agreement* by means of a presumption of consistency with the relevant provisions of the GATT 1994 (and in particular Article XX(b)) for SPS measures conforming to the provisions of the *SPS Agreement*. This means that once a measure has been found to comply with the *SPS Agreement*, its compliance with the GATT 1994 is presumed.

When an SPS measure is at issue, it is therefore logical to examine it under the *SPS Agreement* first, before turning to its conformity with GATT rules. This argument is borne out by the finding of the Panel in *EC - Hormones* in addressing the question of which of these two Agreements it should examine first. It held:

Having reached the conclusion that we are not per se required to address GATT claims prior to those raised under the SPS Agreement, we must then decide which of the two agreements we should examine first in this particular dispute. The SPS Agreement specifically addresses the type of measure in dispute. If we were to examine GATT first, we would in any event need to revert to the SPS Agreement: if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement; if, on the other hand, no GATT violation were found, we would still need to examine the consistency of the measure with the SPS Agreement since nowhere is consistency with GATT presumed to be consistency with the SPS Agreement. For these reasons, and in order to conduct our consideration of this dispute in the most efficient manner, we shall first examine the claims raised under the SPS Agreement.⁷

1.5 Test Your Understanding

1. What requirements must be met for the SPS Agreement to apply to a particular measure?
2. Can SPS standards issued by a non-governmental body be challenged under the *SPS Agreement*? If so, against whom would the dispute be initiated?
3. Would a measure banning the use of toxic plastics in toys for children be regarded as an SPS measure? Why?

⁷ Panel Report, *EC-Hormones (US)*, para. 8.42.

4. Why can one say that the *SPS Agreement* is both wider and narrower than the GATT 1994 in its scope of application?
5. If an SPS measure is found to be in conformity with the *SPS Agreement*, is it then necessary to test its conformity with the *TBT Agreement* and/or the GATT? If an SPS measure were found to be in conformity with the GATT, would it still be necessary to test its conformity with the *SPS Agreement*?

2. BASIC PRINCIPLES OF THE SPS AGREEMENT

On completion of this section the reader will be able:

- to discuss the basic principles of the *SPS Agreement* and their application in dispute settlement.
- to explain the way in which the *SPS Agreement* seeks to balance the right of governments to enact health measures with free trade, in particular, what the limits on the exercise of this right are.
- to identify the basic scientific disciplines introduced by the *SPS Agreement* as well as the existing GATT disciplines taken on board by the *SPS Agreement*.
- to describe how these basic rules are applied in the case law and what their effect is on the burden of proof.
- to demonstrate how the *SPS Agreement* encourages, without obliging, Members to harmonize their SPS measures around international standards, and to assess the implications thereof for developing countries.

2.1 Basic Rights and Obligations

Article 2 SPS

Article 2 of the *SPS Agreement* sets out the basic rights and obligations under the Agreement, which are then further elaborated on in subsequent articles. Article 2 reflects the underlying aim of the *SPS Agreement* of balancing the recognized right of sovereign governments to take measures for the protection of health, with the need to promote free trade and prevent protectionism.

2.2 Right to Take SPS Measures

Article 2.1 SPS

Article 2.1 expressly recognises the *right* of Members to take SPS measures necessary for the protection of human, animal or plant life or health, provided that they conform to the disciplines of the *SPS Agreement*. This is an important provision, as it represents a movement away from the position under the GATT, where in principle discriminatory health measures are prohibited unless they can be justified under the exception in Article XX(b). Thus, under GATT rules the burden of proof rests on the Member imposing the health measure to justify its measure. On the contrary, Article 2.1 of the *SPS Agreement* makes clear that SPS measures are, in principle, allowed and it is for the complaining Member to prove that the measure does not comply with the disciplines of the *SPS Agreement*.

2.3 Limits to the Right to Take SPS Measures

Article 2.2 SPS

The undisputed right of Members to take SPS measures is not unlimited but its exercise is subject to the disciplines set out in the rest of the *SPS Agreement*.

Some of these disciplines contain new scientific justification requirements for SPS measures, whereas others embody familiar GATT rules. These disciplines find their first reflection in Articles 2.2 and 2.3 of the *SPS Agreement* and are further fleshed out in later provisions. Article 2.2 provides:

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5

Article 2.2 lays down two basic requirements for SPS measures, namely that: (1) they be applied only to the extent *necessary* to protect human, animal or plant life or health; and (2) they have a basis in *scientific evidence*, except as provided in Article 5.7.

2.3.1 Necessity Test

The obligation on Members, contained in Article 2.2 of the *SPS Agreement*, to ensure that their SPS measures are applied only to the extent necessary to protect human, animal or plant life or health, reflects the familiar GATT necessity test contained in Article XX(b). As mentioned before, Article XX(b) of the GATT represents an exception to the normal GATT disciplines and thus the burden of proof to show that its requirements are met rests on the Member imposing the health measure. On the contrary, this rule-exception relationship is absent in Article 2.2 of the *SPS Agreement* and it is therefore for the complaining Member to prove that the necessity test is not met.

The necessity test in Article 2.2 has not yet been subject to dispute settlement as complaining parties who bring disputes under the *SPS Agreement* seem to accept readily that the measures in dispute comply with this requirement, or address their challenges to later more specific provisions of the *SPS Agreement*, which could be regarded as further specifications of the necessity test.

2.3.2 Scientific Basis/Evidence

Article 2.2 introduces the first mention of *scientific* disciplines on SPS measures into the *SPS Agreement* and establishes science as the touchstone against which SPS measures will be judged. It requires that SPS measures be based on scientific principles and not be maintained without sufficient scientific evidence, except as provided for in Article 5.7 (which deals with cases where there is insufficient scientific evidence).⁸ This scientific requirement is further elaborated on in Article 5.1, which requires that SPS measures be based on a risk assessment.

⁸ Article 5.7 is dealt with in detail in section 3 below.

The importance of these scientific disciplines in mediating between the competing goals of trade liberalization and health protection was made explicit by the Appellate Body in *EC - Hormones* where it stated:

...The requirements of a risk assessment under Article 5.1, as well as of 'sufficient scientific evidence' under Article 2.2, are essential for the maintenance of the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing interests of promoting international trade and of protecting the life and health of humans...⁹

The crux of the scientific discipline in Article 2.2 is the requirement of “sufficient scientific evidence” for SPS measures. The issue of the meaning of this requirement was raised in *EC - Hormones* but not decided on for reasons of judicial economy. It arose again in *Japan - Agricultural Products*, where the Appellate Body pointed out that “sufficiency” is a relational concept, requiring the existence of an adequate relationship between two elements, in this case the SPS measure and the scientific evidence.¹⁰ It went on to conclude:

...we agree with the Panel that the obligation in Article 2.2 that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship between the SPS measure and the scientific evidence. Whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.¹¹

Therefore, it is clear that panels have some discretion in determining whether a “rational relationship” exists between the SPS measure and scientific evidence, according to the circumstances of the particular case. Panels may examine the quantity and quality of scientific evidence as well as the nature of the SPS measure imposed in coming to their decision. Where there is reputable scientific support for a measure, it would appear that the requirement of a rational relationship between the measure and the scientific evidence is met and thus that there is “sufficient scientific evidence” for the measure.

The burden of proof rests with the complaining party to raise a *prima facie* case that there is no “sufficient scientific evidence” for the measure. In *Japan - Agricultural Products*, the United States claimed that the Panel had imposed an impossible burden of proof on it under Article 2.2 by requiring it to prove a negative, namely that no relevant studies or reports existed to support Japan’s SPS measure (in respect of four of the eight products at issue).¹² The Appellate

⁹ Appellate Body Report, *EC-Hormones* para. 177.

¹⁰ Appellate Body Report, *Japan - Measures Affecting Agricultural Products* (“*Japan - Agricultural Products II*”), WT/DS76/AB/R, adopted 19 March 1999, para. 73.

¹¹ Appellate Body Report, *Japan - Agricultural Products II*, para. 84.

¹² Appellate Body Report, *Japan - Agricultural Products II*, para. 38.

Body rejected the argument of the United States, and held:

...In our view, it would have been sufficient for the United States to raise a presumption that there are no relevant studies or reports. Raising a presumption that there are no relevant studies or reports is not an impossible burden. The United States could have requested Japan, pursuant to Article 5.8 of the SPS Agreement, to provide 'an explanation of the reasons' for its varietal testing requirement, in particular, as it applies to apricots, pears, plums and quince. Japan would, in that case, be obliged to provide such explanation. The failure of Japan to bring forward scientific studies or reports in support of its varietal testing requirement as it applies to apricots, pears, plums and quince, would have been a strong indication that there are no such studies or reports. The United States could also have asked the Panel's experts specific questions as to the existence of relevant scientific studies or reports or it could have submitted to the Panel the opinion of experts consulted by it on this issue.¹³

In *EC - Hormones* the Appellate Body mentioned that in determining whether there is "sufficient scientific evidence" panels should bear in mind that responsible governments act with prudence and precaution when faced with serious risks to human health. It seems from this finding that the more serious the risks, the easier it will be to prove "sufficient scientific evidence".

**Relationship
between Articles
2.2 and 5.7 SPS**

It must be borne in mind that Article 2.2 does take into account the fact that governments sometimes need to act in the face of scientific uncertainty by making express reference to Article 5.7 as an exception to the requirement of "sufficient scientific evidence". Article 5.7¹⁴ has been recognized by the Appellate Body as reflecting the precautionary principle.¹⁵ In *Japan - Agricultural Products* the Appellate Body discussed the relationship between Article 2.2 and Article 5.7, holding that:

...it is clear that Article 5.7 of the SPS Agreement, to which Article 2.2 explicitly refers, is part of the context of the latter provision and should be considered in the interpretation of the obligation not to maintain an SPS measure without sufficient scientific evidence. Article 5.7 allows Members to adopt provisional SPS measures 'in cases where relevant scientific evidence is insufficient' and certain other requirements are fulfilled. Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless.¹⁶

2.3.3 No Arbitrary or Unjustifiable Discrimination or Disguised Restriction on Trade

¹³ Appellate Body Report, *Japan - Agricultural Products II*, para. 137.

¹⁴ The requirements of Article 5.7 will be discussed in section 3 below.

¹⁵ Appellate Body Report, *EC-Hormones*, para. 124.

¹⁶ Appellate Body Report, *Japan - Agricultural Products II*, para. 80.

Article 2.3 SPS

The third basic limitation on the exercise of the right to impose SPS measures is found in Article 2.3 of the *SPS Agreement*. This article embodies certain familiar GATT trade disciplines, which are the non-discrimination provisions of Article I:1 and III:4 of the GATT as well the *chapeau* of Article XX¹⁷ which prevents the application of measures falling within the Article XX exceptions in ways which would “constitute a means of arbitrary or unjustifiable discrimination between countries where the same provisions prevail, or a disguised restriction on international trade.” Article 2.3 provides:

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

Article 2.3 was at issue before the Compliance Panel in *Australia - Salmon* as Canada claimed that Australia had imposed import requirements for salmonids from Canada, but had no internal control measures regarding the movement of dead Australian fish. According to Canada, this constituted arbitrary or unjustifiable discrimination under Article 2.3. The Compliance Panel identified three cumulative requirements for proof of violation of Article 2.3, namely that:

- (1) the measure discriminates either between the territories of Members other than the Member imposing the measure, or between the territory of the Member imposing the measure and another Member;
- (2) the discrimination is arbitrary or unjustifiable; and
- (3) identical or similar conditions prevail in the territories of the Members compared.¹⁸

The first element which must be proved is therefore the existence of discrimination. In *Australia - Salmon* the Compliance Panel held that discrimination under Article 2.3 includes not only discrimination between like products but also discrimination between *different* products (in this case between salmonids from Canada and other dead fish from Australia).¹⁹ This deviates significantly from the non-discrimination rules in the GATT 1994, which only prohibit discrimination between “like”²⁰ or “directly competitive or substitutable”²¹ products. The broader prohibition in Article 2.3 takes into account the fact that different products may pose the same or similar health risks and should therefore be treated in the same way. There could be a possibility for example, that different fruits may be vectors for the same pest or various animals can be carriers of Foot and Mouth Disease.

¹⁷ This fact was expressly stated in Appellate Body Report, *Australia – Measures Affecting Importation of Salmon* (“*Australia – Salmon*”), WT/DS18/AB/R, para. 251.

¹⁸ Compliance Panel Report, *Australia - Salmon*, para. 7.111.

¹⁹ Compliance Panel Report, *Australia - Salmon*, para. 7.112.

²⁰ Article I:1 (Most Favoured Nation Treatment obligation) and Article III:4 (National Treatment obligation) of the GATT 1994.

²¹ Article III:2 of the GATT 1994 (in respect of internal taxes) as explained in the Ad Note thereto.

The breadth of this prohibition on discriminatory treatment is tempered by the other two requirements that must be met before Article 2.3 can be proved to be violated. Namely, the difference in treatment must be arbitrary or unjustifiable *and* identical or similar conditions must prevail in the territories of the Members subject to the different treatment. If the difference in treatment can be justified (for example because the two products compared do not carry the risk of the spread of the same pest or disease) or the conditions in the territories of the Members involved differ, Article 2.3 is not violated.

***Relationship
between Articles
2.3 and 5.5 SPS***

As stated above, the basic disciplines in Article 2 are elaborated on in later articles. In this way, the rule contained in Article 2.3 finds reflection in Article 5.5, which prohibits arbitrary or unjustifiable distinctions in the levels of protection deemed appropriate by a Member in different but comparable situations.

In *EC - Hormones* the Appellate Body noted that Article 5.5 must be read together with Article 2.3 which forms part of its context.²² However, this does not mean that the discipline in Article 2.3 is subsumed into Article 5.5. While a violation of Article 5.5 necessarily implies a violation of Article 2.3, the converse is not true. Article 2.3 contains independent obligations beyond those of Article 5.5. Thus, a violation of Article 2.3 can be found without any examination under Article 5.5.²³

2.4 The Goal of Harmonization

SPS measures vary widely across countries due to the differences in factors which national regulatory authorities take into account in creating SPS measures, such as the interests of domestic industries, consumers' tolerance of risk, climatic and geographical conditions, level of technological development and the economic resources available. However, the resulting diversity of SPS measures has a negative impact on trade as exporters must meet a plethora of standards to gain entry to export markets. This is of particular significance for developing countries which often lack the resources and technical capacity to implement these diverse standards.

The *SPS Agreement* aims to address this problem. In its preamble, one of the primary aims expressed is the promotion of the use of harmonized SPS measures by Members, based on international standards developed by the relevant international organizations, without requiring Members to change what they consider to be an appropriate level of protection.²⁴

Article 3 of the *SPS Agreement* therefore attempts to balance the aim of increasing free trade through harmonizing SPS measures and thus reducing the trade barriers caused by differing standards, with respect for the right of

²² Appellate Body Report, *EC - Hormones*, para. 212.

²³ Compliance Panel Report, *Australia - Salmon*, para. 8.160 and Appellate Body Report, *Australia - Salmon*, para. 252.

²⁴ This aim is expressed in the sixth paragraph of the Preamble to the *SPS Agreement*.

Members to choose their own level of protection. This aim was expressly stated by the Appellate Body in *EC - Hormones* where it held:

In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both 'necessary to protect' human life or health and 'based on scientific principles', and without requiring them to change their appropriate level of protection.²⁵

Harmonization around international standards is encouraged in the *SPS Agreement* by means of a presumption of consistency of measures conforming to international standards with the GATT 1994 and the *SPS Agreement*. However, the adoption of harmonized standards is not actually mandated even though global standards would be most trade efficient. This is in line with the fact that the choice of a level of protection is viewed as a sovereign decision and accorded substantial deference in the *SPS Agreement*. Thus a government is not obliged to adopt an international standard that leads to a level of health protection lower than that which it deems to be appropriate. This strategy is embodied in Article 3 of the *SPS Agreement*.

Under Article 3, Members are given three autonomous options with regard to international harmonised standards, each with its own consequences. Broadly speaking, Members may either (1) base their SPS measures on international standards under Article 3.1; (2) conform their SPS measures to international standards under Article 3.2; or (3) deviate from international standards under Article 3.3. It is important to note that these are equally available alternatives and that there is no rule-exception relationship between them.²⁶ As a result, the burden of proof remains on the complaining Member to show that the requirements under any of the three options are not met.

These three options are examined in more detail below.

2.4.1 Measures Based on International Standards

Article 3.1 SPS

Article 3.1 expresses the aim of harmonizing SPS measures on as wide a basis as possible, and states the obligation of Members to “base” their SPS measures on international standards, guidelines or recommendations, where they exist, except as provided for in Article 3.3.²⁷

²⁵ Appellate Body, *EC – Hormones*, para.177.

²⁶ In *EC-Hormones* the Appellate Body rejected the Panel’s approach of seeing Articles 3.1 and 3.2 as the general rule and Article 3.3 as the exception (Appellate Body Report, *EC – Hormones*, para. 104).

²⁷ Once again, it should be remembered that this last phrase does not mean that Article 3.3 is an exception to the obligation set out in Article 3.1, but that it only serves to exclude from its scope of application measures falling under Article 3.3 (Appellate Body Report, *EC - Hormones*, para. 104).

Annex A.3 SPS

It is necessary to identify what is meant by “international standards, guidelines or recommendations”. The WTO is not a regulatory body with norm-setting capacity. Therefore it cannot set harmonized standards itself, but relies on those set by international standard-setting organizations active in the field of human, animal or plant health. These organizations are identified in Annex A.3 of the *SPS Agreement*, which defines “international standards, guidelines and recommendations” as those set by: (1) the Codex Alimentarius Commission in the area of food safety; (2) the International Office of Epizootics in the area of animal health; (3) the International Plant Protection Convention in the area of plant health; and (4) other relevant international organizations open for membership to all WTO Members, as identified by the SPS Committee, for matters not covered by the three mentioned organizations.

Each of the standard-setting organizations has its own structure and standard-setting procedure. These are dictated by their own statutes and not by the WTO. In general, their activities may be characterised as taking risk management decisions (such as laying down guidelines or setting standards, which embody a certain level of protection) on the basis of scientific information from risk assessments.²⁸ However, the way in which they do this varies considerably. Due to the increased importance of the standards set by these organizations since the coming into force of the *SPS Agreement*, there has been a growing interest in the standard-setting work of these organizations.

“Based on”

Where a relevant international standard, guideline or recommendation exists, Article 3.1 requires that Members “base” their SPS measures on that standard. In *EC - Hormones* the meaning of “based on” was addressed. The Appellate Body stated:

...To read Article 3.1 as requiring Members to harmonize their SPS measures by conforming those measures with international standards, guidelines and recommendations, in the here and now, is, in effect, to vest such international standards, guidelines and recommendations (which are by the terms of the Codex recommendatory in form and nature) with obligatory force and effect. The Panel’s interpretation of Article 3.1 would, in other words, transform those standards, guidelines and recommendations into binding norms. But, as already noted, the SPS Agreement itself sets out no indication of any intent on the part of the Members to do so. We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation by mandating conformity or compliance with such standards, guidelines and recommendations. To sustain such an assumption and to warrant such a far-reaching interpretation, treaty language far more specific and compelling than that found in Article 3 of the SPS Agreement would be necessary.²⁹

The Appellate Body thus made it clear that the voluntary standards set by the

²⁸ The distinction between risk assessment and risk management is discussed in Section 3 below.

²⁹ Appellate Body, *EC-Hormones*, para. 165.

relevant international organizations do not become mandatory through the operation of the *SPS Agreement*.

With regard to the meaning of “based on”, the Appellate Body stated that one thing is commonly said to be based on another if the former stands or is founded or built upon or supported by the latter. Further, it stated that a measure based on a standard does not necessarily conform to that standard, such as where only some but not all the elements of the standard are incorporated into the measure.³⁰

For developing countries, the advantage of basing their SPS measures on international standards comes from the fact that they are often unable to undertake the scientific studies necessary to support their own SPS measures, due to resource constraints. International standards are necessarily based on scientific risk assessments. Therefore, developing country measures that are based thereon, even if they do not conform completely and do not adopt the same measure as the international standard, are based on a risk assessment. If challenged under Article 5.1, which requires that SPS measures be based on a risk assessment, developing countries can then point to the risk assessment that forms the basis for the international standard, and must then only show that their own measure is “based on” this risk assessment.³¹ For this reason, it is to the advantage of developing countries that as many international standards as possible are developed in areas of interest to them.

2.4.2 Measures Conforming to International Standards

Article 3.2 SPS

The second option open to Members, set out in Article 3.2, is to choose to establish an SPS measure which conforms to the relevant international standard, guideline or recommendation. In *EC - Hormones* the Appellate Body explained what is required for a measure to “conform to” an international standard, stating:

“conform to”

*Such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard.*³²

It thus appears that the national measure must be identical to the international standard, both as regards its structure and the level of protection it embodies.

Presumption of consistency

Article 3.2 encourages harmonization by creating a presumption of consistency with the GATT 1994 and the *SPS Agreement* for such conforming measures. This presumption was held to be rebuttable.³³ The Appellate Body in *EC - Hormones* addressed the implications of the presumption of consistency. It stated that the presumption is an *incentive* for Members to conform their SPS

³⁰ Appellate Body Report, *EC – Hormones*, para.163.

³¹ The requirement that an SPS measure be “based on” a risk assessment will be discussed in Section 3 below.

³² Appellate Body, *EC - Hormones*, para. 170.

³³ Appellate Body Report, *EC - Hormones*, para. 170.

measures with international standards, but that Members who decide not to conform their measure to international standards may not be *penalized* by the imposition of a special or generalized burden of proof.³⁴ It is therefore clear that the burden of proof remains on the complaining party to prove a violation of the *SPS Agreement* in either case, but the burden is heavier in respect of conforming SPS measures as the complaining party has to overcome the presumption of consistency contained in Article 3.2.

The presumption of consistency in Article 3.2 holds definite benefits for developing countries. Often developing countries lack the resources to comply with all the disciplines of the *SPS Agreement* when imposing SPS measures. They are thus vulnerable to challenges under the *SPS Agreement*. When their SPS measures conform to international standards, the likelihood that they will be challenged is greatly reduced due to the difficulties involved in overcoming the presumption of consistency contained in Article 3.2. It should be noted that the presumption of consistency extends not only to the scientific disciplines of the *SPS Agreement*, but that the conforming measures will be presumed consistent with the entire *SPS Agreement* as well as the GATT 1994.

2.4.3 Measures Resulting in a Higher Level of Protection

Article 3.3 SPS

The third option open to Members is contained in Article 3.3. Article 3.3 recognizes the right of Members to use SPS measures which result in a higher level of protection than would be achieved by measures “based on” the relevant international standards and sets certain requirements for this. This option is significant in that it recognizes Members’ right to choose their own level of SPS protection, an important principle in the *SPS Agreement*. In *EC - Hormones* the Appellate Body held that:

The right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an ‘exception’ from a ‘general obligation’ under Article 3.1.³⁵

The right to choose measures providing a higher level of protection than international standards is not an “absolute or unqualified right”, as recognized by the Appellate Body in *EC - Hormones*.³⁶ Instead, it is subject to the requirements laid down in Article 3.3, namely that there either be a scientific justification for the measure or that the measure be the result of the higher level of protection chosen by the Member in accordance with Articles 5.1-5.8. In both cases, the measure must be consistent with all other provisions of the *SPS Agreement*.

Although the use of the word “or” would seem to indicate that two different situations are envisaged by Article 3.3 where deviation from international

³⁴ Appellate Body Report, *EC - Hormones*, para. 102.

³⁵ Appellate Body, *EC-Hormones*, para. 172

³⁶ Appellate Body Report, *EC - Hormones*, para.172.

standards is possible, the Appellate Body has recognized that this article is “not a model of clarity in drafting”.³⁷ According to the Appellate Body, the distinction made in Article 3.3 between two situations “may have very limited effects and may, to that extent, be more apparent than real.”³⁸ This is because, on proper interpretation of this provision, a Member that deviates from an existing international standard is *always* obliged to justify its measures by means of a risk assessment.³⁹ In other words, a Member who claims scientific justification for its deviation from an international standard, must base its claim on a proper risk assessment in the same way as must a Member who justifies its deviation on the grounds that it has chosen a different level of protection than that achieved by the international standard. According to the Appellate Body, the requirement of a risk assessment is “intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection.”⁴⁰

2.4.4 Developing Country Participation in International Standard Setting

Articles 3.4 and 10.4 SPS

Members are obliged, under Article 3.4, to participate in the work of the international standard-setting organizations, to the extent that their resources permit, and to promote the development and periodic review of the SPS standards set in these organizations. However, this provision itself recognizes that resources are a limiting factor regarding the participation of Members in international standard-setting organizations.

In fact, much critical attention has been focused on the standard-setting process in these organizations and the problems that developing countries face with regard to effective participation therein.⁴¹ The recognition of this situation is reflected in Article 10.4, which states that Members should encourage and facilitate the active participation of developing country Members in the relevant international standard-setting organizations. There have been initiatives in this regard, but concerns still remain regarding the commitment of developed countries to implementing Article 10.4, which does not impose real obligations on Members but states only that they “should” provide assistance to developing countries in this regard.

In recent years, due to their awareness of the increased importance of international standards under the *SPS Agreement*, the participation of developing countries in the standard-setting organizations has been increasingly active. Their level of attendance has improved and they have become more vocal in ensuring their viewpoints are taken into account in plenary sessions

³⁷ Appellate Body Report, *EC - Hormones*, para.175.

³⁸ Appellate Body Report, *EC - Hormones*, para. 176.

³⁹ In a footnote to Article 3.3, “scientific justification” is defined in a way that indicates that a risk assessment is required (Appellate Body Report, *EC - Hormones*, para. 175).

⁴⁰ Appellate Body Report, *EC - Hormones*, para. 177.

⁴¹ The issue of effective participation should be distinguished from that of Membership in the international standard-setting organizations. In fact, a large majority of WTO Members, including most developing countries, are members of Codex, the OIE and the IPPC. The WTO secretariat has compiled a list in this regard (see G/SPS/GEN/49/Rev.4, dated 30 April 2002).

where standards are decided upon. However, their participation in technical committees where scientific evidence is discussed and standards are prepared often leaves much to be desired. This is often due to the lack of human and financial resources necessary to ensure attendance of the plethora of committee meetings by well-prepared specialists in the areas in which standards are set. In addition, the lack of effective national infrastructures for the evaluation of draft standards and the formulation of positions has been identified as a problem.⁴²

Increasingly there have been concerted efforts to address the problems that developing countries face with regard to effective participation in standard-setting organizations.⁴³ The Directors-General of the FAO, WHO, OIE, WTO and the President of the World Bank issued a statement at the Doha Ministerial Conference in which they affirmed their commitment to strengthening the capacity of developing countries to participate fully in international standard-setting.⁴⁴ However, it is clear that there is still much to be done in this regard.⁴⁵

2.5 Test Your Understanding

1. **Explain the effect of Article 2.1 of the SPS Agreement on the burden of proof in dispute settlement regarding an SPS measure and compare this to the situation of health measures under the GATT 1994.**
2. **What does the requirement of “sufficient scientific evidence” entail?**
3. **WTO Members are not required to adopt internationally agreed SPS standards, guidelines or recommendations. They have in fact three options. Describe these three options and their consequences. Which of these options is often most beneficial to developing country Members?**
4. **Describe the current situation with regard to developing country participation in international standard-setting organizations.**

⁴² G/SPS/GEN/236, dated 9 March 2001.

⁴³ See for example the initiatives described in: G/SPS/GEN/250, dated 14 May 2001.

⁴⁴ WT/MIN(01)/ST/97, dated 11 November 2001.

⁴⁵ In this respect it should be noted that a review of the Codex (and other FAO and WHO work on food standards) has been launched to provide input into decision making on future policies and management. This review will include an evaluation of the particular interests of developing countries as regards their participation in the standard-setting process (see World Health Organization and Food and Agriculture Organization, Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards 16 April 2002, WHO/FAO: Rome/Geneva para. 8(iv)). See also Steve Suppan and Rod Leonard, Comments Submitted to the Independent Evaluation of the Codex Alimentarius and Other FAO-WHO Work on Food Standards, WTO Watch (2002), available at: www.wtowatch.org/library/admin/uploadedfiles/showfile.cfm?FileName=Comments_Submitted_to_the_Independent_Evaluation.htm.

3. RISK ANALYSIS OBLIGATIONS

On completion of this section the reader will be able:

- to identify and discuss the obligations in the *SPS Agreement* that relate to risk analysis and the regulatory process.
- to distinguish between risk assessment and risk management and explain how the disciplines relevant to each are applied in practice.
- to assess the role of the precautionary principle in the *SPS Agreement* as reflected in Article 5.7.

3.1 Aspects of the Regulatory Process

A distinction has been drawn between two aspects of the regulatory process that deal with risk analysis: risk assessment and risk management. Risk assessment can be defined as the science-based process of determining the existence of a risk and the likelihood of it occurring. Risk management, on the other hand, entails a policy-based choice of the level of health protection that a state wants to secure in its territory, and the choice SPS measure to achieve this level of protection. Risk management decisions are based not only on the scientific results of the risk assessment but also on various societal value judgements such as the citizens' tolerance of risk. The distinction between the two aspects of the regulatory process is not absolute, however, and non-scientific elements do play a role in risk assessment. The distinction is only a useful tool to enhance understanding of the regulatory process.

Article 5 SPS

The rules of the *SPS Agreement* relating to the regulatory process, contained in Article 5, have been fashioned in a way that *implicitly* takes this distinction into account when judging the validity of national SPS measures. Strict disciplines are applied to the risk assessment process, whereas a Member's choice of an appropriate level of protection is, to a large extent, respected. However, as noted by the Appellate Body in *EC - Hormones*, there is no express mention of the term "risk management" in the *SPS Agreement* and this conceptual distinction should not be used in a way that is not supported by the actual text of the *SPS Agreement*.⁴⁶

3.2 Risk Assessment

The *SPS Agreement* contains certain disciplines applicable to the risk assessment phase of the regulatory process, which aim to ensure that SPS measures are scientifically justified and take the relevant factors into account. Fundamental to these disciplines is the requirement that Members ensure that their SPS measures are based on a risk assessment.

⁴⁶Appellate Body Report, *EC - Hormones*, para. 181.

3.2.1 Concept of Risk Assessment

Annex A.4 SPS

In order to establish if an SPS measure is based on a risk assessment as required by Article 5.1, it is first necessary to determine what is meant by a risk assessment. Annex A.4 of the *SPS Agreement* defines two types of risk assessments, which correspond to the two broad goals of SPS measures as defined in Annex A.1, namely protection from risks from pests or diseases and protection from food-borne risks.⁴⁷ It is important to determine what type of risk assessment is required in a particular case as the requirements for each type differ.

The first type of risk assessment requires the “evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measure which might be applied, and of the associated potential biological and economic consequences”. The second requires the “evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.” Which definition of risk assessment applies in a given case will depend on what type of SPS measure (defined according to its *goal or purpose*) is at issue.

Risk assessment for food-borne risks

In *EC - Hormones* the SPS measure (the EC’s ban on hormone-treated beef) was aimed at food-borne risks. Thus the second definition of risk assessment was at stake. The Panel had held that there were two requirements for this kind of risk assessment (in this case), namely it should:

- (i) *identify the adverse effects* on human health (if any) arising from the presence of the hormones at issue when used as growth promoters *in meat or meat products*; and
- (ii) if any such adverse effects exist, *evaluate the potential or probability of occurrence of these effects*.⁴⁸

The Appellate Body did not take issue with the two-step test, but disagreed with the Panel’s use of “probability” as an alternative for “potential” as the word seems to introduce a quantitative element to the notion of risk.⁴⁹ The Appellate Body agreed with the Panel⁵⁰ that there must be an “identifiable risk”, not just a theoretical uncertainty (which always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects). However, to the extent that the Panel seemed to require a risk assessment to establish a minimum magnitude of risk, the Appellate Body noted that there is no basis in the *SPS Agreement* for such a quantitative requirement.⁵¹ Thus, although a risk assessment must identify a real risk, this risk need not be quantified but can be expressed qualitatively.

⁴⁷ The definition of SPS measures in Annex A.1 is discussed in Section 1 above.

⁴⁸ Panel Report, *EC – Hormones (Canada)* para. 8.101 and Panel Report, *EC – Hormones (US)*, para. 8.98.

⁴⁹ Appellate Body Report, *EC - Hormones*, paras.184-186.

⁵⁰ Panel Report, *EC – Hormones (Canada)* para. 8.155-156 and Panel Report, *EC – Hormones (US)*, para. 8.152-153.

⁵¹ Appellate Body Report, *EC - Hormones*, para. 186.

Risk assessment for risks from pests or diseases

In *Australia - Salmon* the SPS measure at issue (Australia's ban on fresh, chilled or frozen salmon from Canada) was aimed at preventing the entry, establishment or spread of fish diseases. Thus the first definition of risk assessment was applicable. The Panel held that this type of risk assessment must:

- (1) assess the risk of entry, establishment or spread of a disease; and
- (2) assess the risk of the 'associated potential biological and economic consequences'.⁵²

This differs from the second definition of a risk assessment for food-borne risks as the latter does not involve an evaluation of biological and economic consequences. This is because in cases where human health is at risk, Members cannot be required to weigh up economic considerations.

In order to assess these two elements of risk under the first definition, a three-pronged test must be met.⁵³ Namely, the risk assessment must:

- (1) *identify* the pests or diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
- (2) *evaluate the likelihood* of entry, establishment or spread of these pests or diseases, as well as the associated potential biological and economic consequences; and
- (3) *evaluate the likelihood* of entry, establishment or spread of these diseases *according to the SPS measures which might be applied*.⁵⁴

The Appellate Body in *Australia - Salmon*⁵⁵ pointed to the different language used in the first and second definitions of risk assessment in Annex A. While the second calls for an evaluation of the "potential" for adverse effects, the first requires the evaluation of the "likelihood" of entry, establishment or spread of pests or diseases. The Appellate Body held that "likelihood" means "probability". Thus under this definition of risk assessment it is not sufficient to show a *possibility* of entry, establishment or spread of diseases and associated biological and economic consequences. Instead, the risk assessment must evaluate the "likelihood", i.e., the *probability*, of entry, establishment or spread of diseases and associated biological and economic consequences as well as the "likelihood", i.e., *probability*, of entry, establishment or spread of diseases according to the SPS measures which might be applied.⁵⁶

The Appellate Body disagreed with the Panel that *some* evaluation of the

⁵² Panel Report, *Australia – Measures Affecting Importation of Salmon* ("Australia – Salmon"), WT/DS18/R and Corr.1, para. 8.72.

⁵³ Appellate Body Report, *Australia - Salmon*, para. 121.

⁵⁴ Appellate Body Report, *Australia - Salmon*, para. 121. This test was endorsed by the Appellate Body in *Japan-Agricultural Products* as well as by the Compliance Panel in *Australia-Salmon* (Appellate Body Report, *Japan - Agricultural Products*, para. 112; Compliance Panel Report, *Australia - Salmon*, para. 7.41).

⁵⁵ Appellate Body Report, *Australia – Salmon*, para. 123.

⁵⁶ The first definition was also at issue in *Japan-Agricultural Products* (Appellate Body Report, *Japan - Agricultural Products*, para. 113-114).

likelihood or probability is sufficient, but agreed that the probability may be expressed either quantitatively or qualitatively and that there is no requirement for the risk assessment to establish a certain magnitude or threshold level of degree of risk.⁵⁷

It seems likely that the different terminology in the two definitions of risk assessment was intended to set less stringent requirements in cases where human health is more likely to be at risk, namely where food safety is at issue, than in cases where the risk applies to pests or diseases, which are more likely to affect plants or animals. However, in neither case is a quantified assessment of risk required or does a minimum threshold of risk have to be proved.

Specificity

Aside from the findings regarding the specific requirements of each of the two definitions of risk assessment, the decisions in these cases also address common issues relating to risk assessment in general. One of these issues is the requirement of specificity in the analysis of risk. It is not sufficient for a risk assessment to show a general risk of harm, but the specific kind of risk at stake in the dispute must be shown.⁵⁸

Comprehensive-ness

Further a risk assessment must be comprehensive i.e. it must cover each of the substances at issue.⁵⁹

Relevance of risk assessments for other product categories

It is possible that studies or risk assessments exist in product categories other than the one at issue, which may have relevance to the case at hand. For example, the two product categories could face risks from the same disease agent. However, although a completely new risk assessment may not be necessary for each product category, a risk assessment for one product cannot be regarded as constituting a risk assessment for related product categories.⁶⁰

As appropriate to the circumstances

The requirement that SPS measures be based on a risk assessment is qualified by the phrase “as appropriate to the circumstances.” It has been held that this qualification does not annul or supersede the obligation to base SPS measures on a risk assessment. Instead, it was held to relate to the *manner* in which such risk assessment has to be carried out.⁶¹ This may differ, depending on the source of the risk (e.g. chemical or pathogen), subject of the risk (human, plant or animal), product involved, and country-specific situations regarding the country of origin or destination of the product. What the appropriate manner

⁵⁷ Appellate Body Report, *Australia - Salmon*, paras 123-124.

⁵⁸ In *EC-Hormones* the Appellate Body found that the risk assessments provided by the EC did not focus on or address the particular kind of risk at stake in that case, namely the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes. Thus the studies were not sufficiently specific to the case at hand and did not meet the requirements for a risk assessment (Appellate Body Report, *EC - Hormones*, para. 200).

⁵⁹ In *EC-Hormones* there was an almost complete lack of evidence regarding one of the hormones at issue, MGA. The Panel noted that one of the basic principles of a risk assessment is that it needs to be carried out for each individual substance at issue (Panel Report, *EC – Hormones (Canada)*, para. 8.258 and Panel Report, *EC – Hormones (US)*, para. 8.255). Similarly, the Panel in *Australia – Salmon* had emphasized that a risk assessment must identify and evaluate the risk for any given disease of concern separately, not simply address the overall risk related to the combination of all diseases of concern (Panel Report, *Australia – Salmon*, para.8.74).

⁶⁰ Panel Report, *Australia – Salmon*, para.8.58.

⁶¹ Panel Report, *Australia – Salmon*, para. 8.57.

of conducting a risk assessment is in a specific case, is determined with reference to the opinions of scientific experts and risk assessment techniques established by international standard-setting organizations in the area at issue.⁶² This flexibility in the manner of conducting a risk assessment could be particularly useful to developing countries.

3.2.2 Factors to be taken into Account

Article 5.2 SPS

Although the *SPS Agreement* does not specify a methodology to be used in conducting a risk assessment, aside from requiring Members to take into account the techniques developed by international organizations,⁶³ Article 5 does list certain factors that Members must take into account when making a risk assessment. Article 5.2 lists the relevant scientific and technical considerations, namely: “available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.” From this list it is clear that a risk assessment, for the purposes of the *SPS Agreement*, is not purely scientific (in the sense of laboratory science), but involves consideration of real-world factors that affect risk, such as climatic factors that could contribute to the proliferation of a pest; the vulnerability of an ecology such as that on an island state; the effectiveness of control mechanisms etc.

In *EC - Hormones* the Appellate Body clarified that Article 5.2 is not a closed list, and therefore risks related to detection and control of failure to observe good veterinary practice could also be taken into account as part of the risk assessment. It therefore overruled the Panel’s finding that such considerations were non-scientific and therefore belonged under risk management rather than risk assessment. In this regard, the Appellate Body noted:

*It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.*⁶⁴

Article 5.3 SPS

Article 5.3 lists certain *economic* factors which Members must take into account when assessing risks to animal or plant (not human) life or health, or when choosing the SPS measure to be applied to achieve their chosen level of

⁶² Panel Report, *Australia – Salmon*, para.8.71.

⁶³ The relevant international standard setting organizations have established guidelines on risk assessment techniques. See for example the *Codex Principles and Guidelines for the Conduct of Microbiological Risk Assessment* CAC/GL30, (1999); the *IPPC Guidelines for Pest Risk Analysis. Chapter 2: Pest Risk Assessment*, ISPM 2 (1996); and the *OIE International Animal Health Code, Guidelines for Risk Analysis, Chapter 1.3.2* (2001) and *International Aquatic Animal Health Code, Guidelines for Risk Assessment, Chapter 1.4.2* (2002).

⁶⁴ Appellate Body, *EC-Hormones*, para. 187.

protection. These economic factors are: “the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.” It is significant to note that Members are not obliged to take these factors into account when regulating risks to human life or health as it is recognized that human health has priority above economic considerations.

3.2.3 Requirement that Measures be “based on” a Risk Assessment

Article 5.1 SPS

Article 5.1 sets the requirement that SPS measures be “based on” an assessment of the risks to human, animal or plant life or health, as appropriate to the circumstances and taking into account risk assessment techniques developed by the relevant international organizations.

The meaning of “based on” was discussed in *EC - Hormones*. The Appellate Body found that ‘based on’ refers to a certain *objective relationship* between two elements, namely between the SPS measure and the risk assessment.⁶⁵

The Appellate Body went on to hold that the requirement that an SPS measure be “based on” a risk assessment is a substantive requirement. Article 5.1, read together with Article 2.2, requires that the results of the risk assessment must “sufficiently warrant” or “reasonably support” the relevant SPS measure, and thus that there be a *rational relationship* between the measure and the risk assessment.⁶⁶

Conflicting scientific conclusions

In practice, the situation sometimes arises that risk assessments come to conflicting conclusions. The Appellate Body in *EC - Hormones* addressed this situation and found that a risk assessment need not come to a monolithic conclusion, but can set out both mainstream and diverging scientific opinions.⁶⁷ It further held:

*... In most cases, responsible and representative governments tend to base their legislative and administrative measures on ‘mainstream’ scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship can only be done on a case-to-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects.*⁶⁸

⁶⁵ Appellate Body Report, *EC - Hormones*, para. 189.

⁶⁶ Appellate Body Report, *EC - Hormones*, para. 193.

⁶⁷ Appellate Body Report, *EC - Hormones*, para. 193.

⁶⁸ Appellate Body, *EC-Hormones*, para. 194.

Borrowed risk assessments

The Appellate Body further noted that 5.1 does not require a Member to conduct its own risk assessment. Instead Members may base their measures on other relevant assessments, such as those carried out by another Member, or an international organization, “as appropriate to the circumstances”.⁶⁹ This finding means that developing countries, many of whom experience problems in conducting their own risk assessments due to resource constraints, may base their measures on risk assessments of other Members or international organizations. However, it should be noted that these borrowed risk assessments should address the risk situation actually faced by the Member imposing the measure (i.e. the relevant environmental conditions, inspection methods, potential damage etc.) in order to meet the requirements of Articles 5.2 and 5.3.

Measures preceding risk assessments

It is also important to determine *when* the risk assessment needs to have been made in order for a measure to be “based” thereon. Obviously there is a multitude of SPS measures that were in existence long before the coming into force of the *SPS Agreement*. It is possible that many of these were not based on a risk assessment, particularly in Members whose resources are too scarce to permit them to undertake thorough risk assessments before enacting SPS measures. The Panel in *EC - Hormones* noted it is possible for an SPS measure enacted before the entry into force of the *SPS Agreement* to be based on a risk assessment carried out after this date. However, this does not excuse a Member from the obligation to base its measure on a risk assessment.⁷⁰ The Appellate Body in that case confirmed this finding.⁷¹

3.3 Risk Management

As discussed above, the *SPS Agreement* gives national regulators broad latitude to take risk management decisions, such as determining the appropriate level of protection they will aim at and choosing the SPS measures they will impose to achieve this level of protection. However, there are certain, non-scientific disciplines that apply to the exercise of these choices.

3.3.1 Right to Determine the Appropriate Level of Protection

Annex A.5 SPS

The concept of “appropriate level of protection” is defined in Annex A paragraph 5 as the level of protection *deemed appropriate by the Member* imposing the measure. It is therefore clear that it is the prerogative of a Member to decide what level of protection of human, animal and plant life or health it will aim at in its territory. This choice is usually made on the basis of scientific information as well as other considerations such as producer and consumer preferences. The *SPS Agreement* does not compel a Member to accept a level

⁶⁹ Appellate Body Report, *EC - Hormones*, para. 190. However, the Appellate Body did require that proof that a risk assessment supporting the measure does exist, be produced at dispute-settlement proceedings.

⁷⁰ Panel Report, *EC – Hormones (Canada)*, para. 8.102 and Panel Report, *EC – Hormones (US)*, para. 8.99.

⁷¹ Appellate Body Report, *EC - Hormones*, para. 129.

of protection lower than the one it has chosen, even if this would be more trade efficient.

It is important to distinguish carefully between the risk assessed in a risk assessment and the appropriate level of protection aimed at. This fact was noted by the Appellate Body in *Australia - Salmon*, where it rejected the Panel's finding that Members may not aim at "zero risk".⁷² The Appellate Body distinguished the "risk" evaluated in a risk assessment, which must be an identifiable risk and not just a theoretical uncertainty (as discussed above), and the "appropriate level of protection" chosen, which may be a zero-risk level.⁷³ Clearly, once it is established that there is scientific evidence of risk, Members are free to choose their own appropriate level of protection.

3.3.2 Minimizing Negative Trade Effects

Article 5.4 SPS

Article 5.4 provides that Members *should* take into account the objective of minimizing negative trade effects, when choosing their appropriate level of protection. The use of the word "should" rather than "shall" indicates that it is a purely hortative provision, containing no binding obligation on Members but merely encouraging them to consider the trade effects of their choice of level of protection.⁷⁴ Clearly, obliging Members to choose the least trade restrictive level of protection would go against the underlying principle of the *SPS Agreement* that recognizes the right of Members to determine the level of protection they want to secure within their territories.

3.3.3 Avoidance of Arbitrary or Unjustifiable Distinctions leading to Discrimination/Disguised Restrictions on Trade

Article 5.5 SPS

Unlike Article 5.4, Article 5.5 of the *SPS Agreement* contains a binding obligation, which disciplines Members' choice of appropriate level of protection. Article 5.5 provides:

With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

⁷² Panel Report, *Australia - Salmon*, para. 8.81.

⁷³ Appellate Body Report, *Australia - Salmon*, para. 125.

⁷⁴ This was recognized by the Panel in *EC-Hormones* (Panel Report, *EC - Hormones (Canada)*, para. 8.169 and Panel Report, *EC - Hormones (US)*, para. 8.166).

It is necessary to determine what precisely the discipline embodied in Article 5.5 entails. Two elements of Article 5.5 can be distinguished, namely:

- (1) the *goal* of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection; and
- (2) the *legal obligation* to avoid arbitrary or unjustifiable distinctions in the levels of protection considered to be appropriate in different situations, if these distinctions result in discrimination or disguised trade restrictions.

Regarding the first element, the Appellate Body in *EC - Hormones* noted that it sets a goal to be achieved in the *future* and does not establish a *legal obligation* of consistency of appropriate levels of protection. Further, it recognized that governments often establish their appropriate levels of protection on a case-by-case basis over time as risks arise, thus the goal is not absolute or perfect consistency, but only the avoidance of arbitrary or unjustifiable inconsistencies.⁷⁵

Regarding the second element, which does create an immediate obligation on Members, the Appellate Body in *EC - Hormones*⁷⁶ set out the requirements required for a violation to be shown. These are that:

- (1) the Member has set its own level of protection in different situations;
- (2) the levels of protection show arbitrary or unjustifiable differences in their treatment of different situations; and
- (3) these arbitrary or unjustifiable differences lead to discrimination or a disguised restriction on trade (referring to the effect of the measure used to reflect the particular level of protection).⁷⁷

These requirements were found to be *cumulative*, thus proof of different treatment of different situations is not sufficient, though it might serve as a warning signal that the measure might be discriminatory or a disguised restriction on trade.

Different situations

It is obvious that not all health risks can or should be treated the same. Thus, with regard to the first requirement for proving a violation of Article 5.5, the Appellate Body in *EC - Hormones* found that to compare the different levels of protection deemed appropriate by a Member, the different situations dealt with must be *comparable*, that is, have some common element or elements.⁷⁸ In *Australia - Salmon*, the Appellate Body noted that situations involving a risk of entry, establishment or spread of the same or a similar disease or a risk of the same or similar associated potential biological and economic consequences are *comparable* under Article 5.5.⁷⁹

⁷⁵ Appellate Body Report, *EC - Hormones*, para. 213.

⁷⁶ Appellate Body Report, *EC - Hormones*, paras 214-215.

⁷⁷ These elements were reiterated in Appellate Body Report, *Australia - Salmon*, para. 140.

⁷⁸ Appellate Body Report, *EC - Hormones*, para. 217.

⁷⁹ In *EC-Hormones* the Panel addressed the comparability of different situations (Panel Report, *EC - Hormones (Canada)*, paras 8.190, 8.215 and 8.224 and Panel Report, *EC - Hormones (US)*, paras 8.186, 8.212 and 8.221). The Appellate Body did not decide on the comparability of the situations identified by the Panel. In *Australia-Salmon* the Appellate Body found two situations where different levels of protection had been adopted comparable (Appellate Body Report, *Australia - Salmon*, para. 153).

To establish if the first requirement has been met, it is further necessary to determine whether Member has imposed *different* levels of protection in different (but comparable) situations. In *Australia – Salmon*, the Panel held that the level of protection is normally reflected in the SPS measure imposed and assumed that if there is a difference in the sanitary *measures* imposed for the different situations compared under Article 5.5, this difference reflects a distinction in *levels of protection*.⁸⁰ However, in dealing with the determination of the appropriate level of protection under Article 5.6, the Appellate Body in *Australia - Salmon* noted that nothing in the *SPS Agreement* or the DSU permits a panel or the Appellate Body to imply the Member's appropriate level of protection from the measure it applies to attain that level of protection.⁸¹ Only if a Member does not express its chosen level of protection or does so insufficiently clearly to enable the application of the relevant provisions of the *SPS Agreement*, may its level of protection be implied from the measures it imposes.

**Arbitrary or
unjustifiable
differences**

Regarding the second requirement, namely that of arbitrary or unjustifiable differences in the levels of protection, the panels and the Appellate Body examine whether there are reasons to justify the differences in levels of protection. For example, they may examine whether the two situations compared involve different levels of risk,⁸² whether the difficulty of controlling the risk differs in each case⁸³ or whether the degree of government intervention necessary to achieve the same level of protection in each case differs.⁸⁴

**Discrimination or
disguised restriction
on trade**

The third and “most important”⁸⁵ requirement to show a violation of Article 5.5 is that the arbitrary or unjustifiable distinctions in levels of protection result in discrimination or a disguised restriction on trade. From the case law, it is possible to identify certain “warning signals” which are not conclusive in their own right, but that taken *cumulatively* and with other factors *may* support the finding that the third requirement of Article 5.5 was met.⁸⁶ However, this depends on the circumstances of each case.

The three warning signals identified by the Panel in *Australia - Salmon*, and which the Appellate Body in that case agreed with,⁸⁷ were:

- (1) the arbitrary character of the differences in levels of protection (i.e. that the second requirement of Article 5.5 is met);⁸⁸

⁸⁰ Panel Report, *Australia – Salmon*, paras. 8.123-8.124.

⁸¹ Appellate Body Report, *Australia - Salmon*, paras 199-200. This issue is dealt with further later in this section.

⁸² In *Australia-Salmon* the differences in risk involved were examined (Panel Report, *Australia - Salmon*, para. 8.137-141 and Appellate Body Report, *Australia – Salmon*, para. 158).

⁸³ Appellate Body Report, *EC - Hormones*, paras 221-225.

⁸⁴ Appellate Body Report, *EC - Hormones*, para. 221.

⁸⁵ Appellate Body Report, *EC - Hormones*, para. 240.

⁸⁶ In *Australia – Salmon*, the Panel had found a violation of the third requirement of Article 5.5 on the basis of these three “warning signals” and three “other factors more substantial in nature” taken cumulatively (Panel Report, *Australia – Salmon*, paras 8.149-8.159.). The first two warning signals were also relied upon in *EC-Hormones* (Appellate Body Report, *EC - Hormones*, paras.215 and 240).

⁸⁷ Appellate Body Report, *Australia – Salmon*, para.162-166.

⁸⁸ Panel Report, *Australia – Salmon*, para.8.149; also mentioned in Appellate Body Report, *EC - Hormones*, para. 215.

- (2) rather substantial difference in levels of protection;⁸⁹ and
- (3) the absence of scientific justification (based on earlier findings of inconsistency with Articles 5.1 and 2.2) which indicates that the measure at issue constitutes a restriction on international trade, disguised as a sanitary measure.⁹⁰

In *EC - Hormones* the *objectives* of the measure were also examined by the Panel and the Appellate Body, in order to determine whether there was discrimination or a disguised restriction on trade and they came to different conclusions on this point.⁹¹

***Relationship with
Article 2.3 SPS***

The Panel and Appellate Body in *EC - Hormones* found that Article 5.5 must be read together with the basic obligation of Members to avoid discrimination and disguised restrictions on trade in Article 2.3.⁹²

***Guidelines for
implementation of
Article 5.5 SPS***

After five years of deliberation, at its meeting of 21-22 June 2000, the SPS Committee adopted guidelines for the implementation of Article 5.5.⁹³ The clarifications resulting from the case law on this point are reflected in the guidelines. In particular, the cumulative presence of the three above-mentioned “warning signals” is stated to be a possible indication of a violation of Article 5.5.

The guidelines are not legally binding but are intended as aids to assist officials in applying Article 5.5 when deciding on appropriate levels of protection or adopting and implementing SPS measures. The guidelines will be reviewed periodically, the first review to be undertaken within 36 months of their adoption.

3.3.4 Least Trade-Restrictive Measure

Article 5.6 SPS

Risk management decisions taken by governments involve not only the choice of an appropriate level of protection, but also the choice of an SPS measure to achieve this level of protection. Article 5.6 disciplines the choice of SPS measure. It obliges Members to ensure that their SPS measures are not more trade restrictive than required to achieve their appropriate level of protection, taking into account technical and economic feasibility. This amounts to a discipline on the choice of measure rather than on the selection of an appropriate level of protection.

In a footnote to this article, the concept of “a measure not more trade restrictive than required” is defined. In *Australia - Salmon* the Appellate Body agreed

⁸⁹ Panel Report, *Australia – Salmon*, para.8.150; also mentioned in Appellate Body Report, *EC - Hormones*, para. 240.

⁹⁰ Panel Report, *Australia – Salmon*, para.8.151; also mentioned in Panel Report, *EC – Hormones (Canada)*, para. 8.244 and Panel Report, *EC – Hormones (US)*, para. 8.241.

⁹¹ Panel Report, *EC – Hormones (Canada)*, para. 8.245 and Panel Report, *EC – Hormones (US)*, para. 8.242. Contra Appellate Body Report, *EC - Hormones*, para. 245.

⁹² Appellate Body Report, *EC - Hormones*, para. 212. This point is discussed further in section 2 above.

⁹³ G/SPS/15, dated 18 July 2000.

with the Panel⁹⁴ that this footnote contains a three-pronged test.⁹⁵ Namely, a measure is more trade restrictive than required only if there is another SPS measure which:

- (a) is reasonably available taking into account technical and economic feasibility;
- (b) achieves the Member's appropriate level of sanitary protection; and
- (c) is significantly less trade restrictive than the contested measure.

The Appellate Body noted that the three elements are *cumulative* in the sense that, to establish inconsistency with Article 5.6, all of them have to be met.⁹⁶

Reasonably available

To show a violation of Article 5.6, the complaining party must prove that an alternative measure exists that is "reasonably available taking into account technical and economic feasibility". This recognition of the fact that a less trade restrictive measure could have high regulatory or compliance costs or could be impractical to implement is particularly significant for developing countries. They will thus not be required to adopt less trade restrictive measures in cases where they do not have the resources or technical capacity to do so.

Achieves appropriate level of protection

In order to show a violation of Article 5.6, a Member must prove that the alternative measures achieve the importing Member's appropriate level of protection. This is important as the *SPS Agreement* recognizes that Members have the prerogative to set their own level of protection and cannot be required to lower it even if less trade restrictive alternatives exist.

It is thus necessary to determine what the appropriate level of protection is in order to be able to apply this provision. The choice of level of protection is the sole prerogative of national decision-makers. Thus alternative measures must always be judged against the Members own chosen level of protection and not simply compared to the measure currently in place. There are, however, cases where Members either do not explicitly state what level of protection they have chosen, or do so in such a vague manner that it is impossible to apply Article 5.6. The Appellate Body has thus held that there is an implied obligation in the *SPS Agreement* on Members to determine their level of protection. Only in cases where a government does not adequately determine its level of protection, may a panel infer it from the measure applied in order to prevent the avoidance of disciplines under the *SPS Agreement*.⁹⁷

Significantly less trade restrictive

The third requirement for a violation of Article 5.6 is that the available alternative measure be "significantly less restrictive to trade" than the measure actually applied. It is notable that the alternative measure must be *significantly* less trade-restrictive before a Member's measure will be deemed "more trade-

⁹⁴ Panel Report, *Australia - Salmon*, para. 95.

⁹⁵ Appellate Body Report, *Australia - Salmon*, para. 194.

⁹⁶ Appellate Body Report, *Australia - Salmon*, para. 194. This finding was reiterated in Appellate Body Report, *Japan - Agricultural Products*, para. 95.

⁹⁷ Appellate Body Report, *Australia - Salmon*, paras. 205-207.

restrictive than required.” Thus a small difference in the trade impacts of the two measures is not sufficient to oblige a Member to adopt the alternative measure.⁹⁸

3.4 Provisional Measures and the Precautionary Principle

Precautionary principle

It is generally accepted that there are situations where governments need to take measures to prevent risks to health even when sufficient scientific evidence regarding the risk is lacking. Thus, governments may act with precaution in order to protect against risks without waiting for the conclusive results of scientific analyses. This is commonly referred to as acting in accordance with the precautionary principle or the precautionary approach.

The extent to which the precautionary principle is taken into account in the *SPS Agreement* is shown below. Article 5.7 of the *SPS Agreement* allows for provisional measures when there is insufficient scientific evidence, under certain conditions, and thus could be said to reflect the precautionary principle. In *EC - Hormones*, the EC had categorized its SPS measure as final, rather than provisional, so it could not rely on Article 5.7. Instead it had tried to rely on the precautionary principle outside the framework of Article 5.7, as a general customary rule of international law or at least a general principle of law, applicable to the interpretation of the scientific disciplines in the *SPS Agreement*.

The Appellate Body expressed its doubts as to whether the precautionary principle has developed into a principle of general or customary international law, outside the field of international environmental law, but found it unnecessary to decide this issue.⁹⁹ The Appellate Body then held that the precautionary principle could not override the explicit requirements of Articles 5.1 and 5.2, in cases of scientific uncertainty.¹⁰⁰ On the relationship between the “precautionary principle” and the *SPS Agreement*, the Appellate Body noted the following four elements:

First, the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement. We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of



⁹⁸ This requirement was examined by both the Panel and the compliance Panel in *Australia-Salmon* and the Panel in *Japan-Agricultural Products* (see Panel Report, *Australia – Salmon*, para. 8.182; Compliance Panel Report, *Australia – Salmon*, paras. 7.150–7.153; and Panel Report, *Japan – Measures Affecting Agricultural Products WT/DS76/R*, paras. 8.79, 8.89, 8.95–8.96 and 8.103–8.104).

⁹⁹ Appellate Body Report, *EC –Hormones*, para. 123.

¹⁰⁰ Appellate Body Report, *EC –Hormones*, para. 125, where it held, “We accordingly agree with the finding of the Panel that the precautionary principle does not override the provisions of the *SPS Agreement*.”

sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether ‘sufficient scientific evidence’ exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.¹⁰¹

Article 5.7 SPS

Thus, it is clear that Members that wish to impose SPS measures in the absence of sufficient scientific evidence must do so in accordance with Article 5.7 and cannot rely on an overriding “precautionary principle” to soften the scientific disciplines of the *SPS Agreement*. In *Japan - Agricultural Products*, the Appellate Body held that Article 5.7 represents a “qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence.”¹⁰² It is therefore necessary to examine what the requirements under Article 5.7 are. It provides:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

The Appellate Body in *Japan - Agricultural Products* identified four requirements for provisional measures under Article 5.7, namely that the measure must:

- (1) be imposed in respect of a situation where “relevant scientific information is insufficient”;
- (2) be adopted “on the basis of available pertinent information”;
- (3) not be maintained unless the Member seeks to “obtain the additional information necessary for a more objective assessment of risk”; and
- (4) be reviewed accordingly “within a reasonable period of time”.

These requirements were held to be *cumulative*. Thus, all four conditions of Article 5.7 must be met in order to avoid the scientific disciplines of Articles 2.2 and 5.1 of the *SPS Agreement*.

¹⁰¹ Appellate Body, *EC-Hormones*, para. 124

¹⁰² Appellate Body Report, *Japan- Agricultural Products*, para. 80.

3.4.1 *Insufficient Relevant Scientific Evidence*

The first requirement, namely that “relevant scientific evidence is insufficient”, must be met for Article 5.7 to apply.¹⁰³ It is thus crucial to determine in what circumstances this criterion will be met. The Panel in *Japan - Agricultural Products*, the only case so far where Article 5.7 was relied upon, found it unnecessary to decide on this issue for reasons of judicial economy, which the Appellate Body agreed with. There is thus no guidance in the case law with regard to the interpretation of this requirement.

3.4.2 *Based on Available Pertinent Information*

The second criterion contained in Article 5.7 requires that the provisional measure be adopted “on the basis of available pertinent information.” Judicial economy also precluded the examination of this requirement in *Japan - Agricultural Products*.

3.4.3 *Obligation to Obtain Necessary Additional Information*

Article 5.7 further prohibits the maintenance of a provisional measure unless a Member “seeks to obtain the information necessary for a more objective assessment of the risk.”

In *Japan - Agricultural Products*, the Appellate Body held in this regard:

*Neither Article 5.7 nor any other provision of the SPS Agreement sets out explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what actual results must be achieved; the obligation is to ‘seek to obtain’ additional information. However, Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct ‘a more objective assessment of risk’. Therefore, the information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, in casu, a pest, according to the SPS measures which might be applied. We note that the Panel found that the information collected by Japan does not ‘examine the appropriateness’ of the SPS measure at issue and does not address the core issue as to whether ‘varietal characteristics cause a divergency in quarantine efficacy’. In the light of this finding, we agree with the Panel that Japan did not seek to obtain the additional information necessary for a more objective risk assessment.*¹⁰⁴

3.4.4 *Review within a Reasonable Period of Time*

The last requirement contained in Article 5.7 refers to the obligation to review

¹⁰³ It should, however, be noted that neither the Panel nor the Appellate Body in *Japan-Agricultural Products* began by determining whether this requirement was met and thus Article 5.7 was applicable to the case.

¹⁰⁴ Appellate Body, *Japan - Agricultural Products*, para. 92.

the measure within a “reasonable period of time.” Thus Article 5.7 creates only a time-limited exemption from the normal SPS disciplines, pending review of the measure in the light of new evidence.

The Appellate Body in *Japan - Agricultural Products* had to decide on what constitutes a “reasonable period of time” within which to review the measure. The Appellate Body held that this has to be established on a case-by-case basis with regard to the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure. The Appellate Body’s finding that one of the factors to be considered in a given case is the difficulty of obtaining the additional information necessary for the review is significant. Clearly, the state of scientific knowledge has a direct impact on the difficulty of obtaining the required information and would thus affect the determination whether a “reasonable period” has elapsed. This is important in that it waters down the temporary nature of measures allowed under Article 5.7 and makes provision for circumstances where scientific uncertainty persists for extended periods or where the risks involved are expected to materialize only in the long term. Therefore, artificially linking the requirement of review within a “reasonable period of time” to specific deadlines is avoided. In this way, Members need not fear that reliance on Article 5.7 to justify their measures will compromise their ability to maintain the measure as long as is necessary for scientific evidence to come up with clear answers.

On the other hand, it is important to note that the difficulty of obtaining information is not the sole criterion. The specific circumstances of the case will be evaluated, including factors such as the characteristics of the SPS measure at stake, amongst others, in order to establish whether this criterion has been met.

3.5 Test Your Understanding

1. Distinguish when each of the definitions of a risk assessment would apply and set out the requirements for each.
2. Describe the limits to the exercise of the right of a Member to set its own appropriate level of protection and explain whether they could result in a Member being forced to lower its appropriate level of protection.
3. If a Member wants to impose SPS measures in a situation of scientific uncertainty, what are the requirements it must meet? Can these requirements be softened by reliance on the precautionary principle?

4. OTHER SUBSTANTIVE PROVISIONS

After completing this section the reader will be able:

- to identify the obligations relating to the recognition of equivalence of different SPS measures as well as those obligations concerned with the adaptation of SPS measures to regional conditions.
- to assess the potential benefits of these provisions for developing countries and to identify problems with their implementation.

4.1 Equivalence

Article 4 SPS

Harmonization of SPS measures around international standards is not always possible or desirable as local conditions, consumer preferences and technical capacity differ between countries. In addition, there are many areas where no international standards yet exist. In all these cases, exporters are faced with a variety of different SPS standards that they must meet to gain access to markets. This variety of SPS standards has a negative impact on trade.

This negative impact on trade of divergent SPS measures can be reduced by recognizing that these different SPS measures may be equally effective in reducing risk, and thus achieve the same level of protection. Article 4 of the *SPS Agreement* sets out the obligations of Members with regard to the recognition of equivalence.

4.1.1 Acceptance of Equivalence

Article 4.1 SPS

The recognition of equivalence most often occurs on an *ad hoc* basis and is not reflected in formal equivalence agreements. Article 4.1 promotes the recognition of equivalence by obliging Members to accept different SPS measures as equivalent, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the appropriate level of protection of the importing Member. For this purpose, the importing Member must be given reasonable access, upon request, for inspection, testing and other relevant procedures.

4.1.2 Agreements on Recognition of Equivalence

Article 4.2 SPS

In practice, it is possible for the recognition of equivalence to be negotiated and embodied in bilateral, regional or multilateral agreements, in which criteria are set out for the acceptance of different SPS measures as equivalent, either on a systems-wide or product-by-product basis. Article 4.2 encourages the conclusion of equivalence agreements by obliging Members to enter into consultations, upon request, with the aim of achieving bilateral and multilateral agreements on the recognition of equivalence of specified SPS measures. However, there is no obligation to actually conclude such agreements.

4.1.3 *Significance of Recognition of Equivalence for Developing Countries*

If importing countries recognize that various measures can achieve the same level of protection and are thus equivalent, the fact that developing countries have different capabilities regarding the imposition and control of SPS measures need not result in the rejection of their agricultural and food products in their export markets. For this reason, Article 4 could go a long way towards improving market access for food and agricultural products from developing countries.

4.1.4 *Problems of Implementation Faced by Developing Countries*

Concerns have been raised by developing countries regarding the implementation of Article 4 of the *SPS Agreement*. They claim that developed countries require “sameness” rather than equivalence of SPS standards and control and inspection systems. This deprives developing countries of the flexibility in the choice of measures that Article 4 aims to achieve. At present the recognition of equivalence by means of agreements takes place in very limited cases, and mostly between developed countries.

Developing countries have also criticised the lack of an obligation in the *SPS Agreement* to notify bilateral or multilateral agreements reached on equivalence.¹⁰⁵ Such an obligation would enable developing country Members that can comply with the conditions set in such agreement to become a party to the existing agreement or conclude a similar bilateral agreement with the importing country. However, it has been noted that Members’ Enquiry Points are obliged to provide answers to questions regarding equivalence agreements.¹⁰⁶ The WTO Secretariat has proposed a format for the notification of equivalence agreements.¹⁰⁷

Some Members, particularly developed countries, hold the view that the negotiation of equivalence agreements is too costly and resource intensive for the limited trade benefits to be gained therefrom. Thus, they advocate recourse to other provisions of the *SPS Agreement* which yield more immediate gains in market access, such as the rules on risk assessment, transparency, technical assistance and control and inspection procedures.¹⁰⁸ Developing countries counter that the burden of negotiating an equivalence agreement is justified as the improved market access gained thereby can be very important for developing countries, especially as their exports are often concentrated in a few products and enterprises.¹⁰⁹

¹⁰⁵ G/SPS/W/111, dated 4 July 2001.

¹⁰⁶ This obligation is contained in Annex B.3(d) and was confirmed by the SPS Committee at its meeting of March 2001 (*Ibid.*, para. 8).

¹⁰⁷ G/SPS/W/114/Rev.1.

¹⁰⁸ G/SPS/W/111, dated 4 July 2001.

¹⁰⁹ *Ibid.*, para. 6.

4.1.5 *Equivalence Decision*

The problems with implementation of Article 4 were referred to the SPS Committee by the General Council.¹¹⁰ In October 2001, the SPS Committee adopted the *Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures*,¹¹¹ commonly known as the *Equivalence Decision*. This Decision sets out some guidelines for any Member who requests the recognition of equivalence of their SPS measures and for the importing Member who is the addressee of such a request.

In particular, the importing Member should, on request, supply information regarding the aim of its SPS measure, the risks it addresses, the appropriate level of protection chosen by the Member, and the underlying risk assessment for the measure. It must respond in a timely manner to the request for recognition of equivalence. The exporting Member must provide science-based and technical information to show that its measure achieves the level of protection chosen by the importing Member and provide reasonable access for testing and inspection. The importing Member should evaluate the scientific and technical information with a view to determining if the SPS measure of the exporting Member achieves its level of protection and must give full consideration to requests for technical assistance for the implementation of Article 4.¹¹²

4.2 *Adaptation to Regional Conditions*

The prevalence of pests and diseases is not determined by national boundaries, and may differ between various regions within a country. This may be the case either due to variations in climatic, environmental or geographic conditions within a country or due to the efforts of the regulatory authorities to eradicate a pest or disease from specific areas. In practice, however, it is common to ban products from an entire country where it has been established that a pest or disease of significance for the importing country occurs, even if its prevalence is limited to certain regions. If importing countries adapt their SPS measures to the conditions prevailing in the region of origin of the product, this may greatly improve market access possibilities. This possibility is significant for developing countries, especially large countries where conditions vary greatly from region to region, as the costs of eradicating a pest or disease or keeping a region pest- or disease-free can be limited by focusing on specific areas.

Article 6.1 SPS

In order to ensure that an area is free of pests or diseases and to prove that this is so, countries often have to invest large amounts of money and resources and comply with lengthy procedures. Thus, in order to make the investment worthwhile, countries need to be sure that their efforts will result in increased

¹¹⁰ WT/GC/M/59, dated 18 October 2000.

¹¹¹ G/SPS/19, dated 24 October 2001.

¹¹² This technical assistance may be in the form of help in identifying and implementing equivalent measures, otherwise enhancing market access opportunities or the development and provision of science-based information to support the recognition of equivalence request.

market access. Article 6.1 aims to provide this security by obliging Members to ensure that their SPS measures are adapted to the sanitary or phytosanitary characteristics of the region of origin of the product or the region to which it is destined.

4.2.1 Factors to be Taken into Account

In determining what the sanitary or phytosanitary characteristics of a region are, Article 6.1 obliges Members to take into account the level of prevalence of specific pests or diseases, the existence of eradication or control programmes and guidelines developed by international organizations. However, the list of factors in Article 6.1 is not exhaustive.

4.2.2 Pest- or Disease-free Areas or Areas of Low Pest or Disease Prevalence

Article 6.2 SPS

Article 6.2 specifically creates the obligation on Members to recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. These areas shall be determined with regard to factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of SPS controls.

4.2.3 Obligations on Exporting Members

Article 6.3 SPS

An exporting Member that claims that regions within its territory are pest- or disease-free or have low pest or disease prevalence must provide the necessary evidence of this fact to the importing Member. For this purpose, it must give the importing Member reasonable access for inspection, testing and other relevant procedures.

4.3 Test Your Understanding

- 1. Discuss why the rules on recognition of equivalence could be to the benefit of developing countries and mention how problems with implementation of this provision are being addressed.**
- 2. Explain what is entailed by the obligation of adaptation to regional conditions and what obligations rest on exporting Members who claim pest- or disease-free status.**

5. INSTITUTIONAL AND PROCEDURAL PROVISIONS

On completion of this section the reader will be able:

- to discuss the operation of the institutional and procedural provisions of the *SPS Agreement* and specifically, the transparency and notification obligations on Members as well as the disciplines on Members' use of control, inspection and approval procedures.
- to evaluate the role of the SPS Committee and to identify those aspects of the WTO dispute settlement procedure specific to the *SPS Agreement*.

5.1 Transparency and Notification

A significant hurdle faced by exporters is the lack of transparency regarding SPS measures on their export markets. SPS measures are often complex and subject to change, leading to lack of certainty for exporters. Finding out about the SPS measures they have to comply with is often a costly and burdensome process for exporters. In addition, in order to identify which SPS measures are unjustified and subject to challenge under the SPS Agreement, details regarding these measures are necessary. For this reason, transparency and notification obligations are crucial in ensuring market access.

5.1.1 Publication and Notification Obligations

Article 7 SPS

Under Article 7 of the *SPS Agreement*, Members are obliged to notify changes in their SPS measures and must provide information on their SPS measures in accordance with Annex B.

Annex B.1 and 5-11 SPS

In terms of Annex B.1, Members must publish all adopted SPS regulations in a way that enables all interested Members to become acquainted with them. A footnote to this paragraph defines SPS regulations as SPS measures such as laws, decrees or ordinances of general application. The Appellate Body in *Japan - Agricultural Products* noted as follows with respect to this footnote:¹¹³

We consider that the list of instruments contained in the footnote to paragraph 1 of Annex B is, as is indicated by the words 'such as', not exhaustive in nature. The scope of application of the publication requirement is not limited to 'laws, decrees or ordinances', but also includes, in our opinion, other instruments which are applicable generally and are similar in character to the instruments explicitly referred to in the illustrative list of the footnote to paragraph 1 of Annex B. The object and purpose of paragraph 1 of Annex B is 'to enable interested Members to become acquainted with' the sanitary and phytosanitary regulations adopted or maintained by other Members and thus to enhance transparency regarding these measures. In our opinion, the scope of application of the



¹¹³ Appellate Body Report, *Japan - Agricultural Products II*, paras. 105-108.

publication requirement of paragraph 1 of Annex B should be interpreted in the light of the object and purpose of this provision.¹¹⁴

Where no international standards exist or where a proposed SPS measure is not substantially the same as the international standard, and the measure may have a significant effect on trade, Annex B.5 sets out the notification procedure to be followed for new SPS measures.¹¹⁵ Under this procedure, other Members are allowed a reasonable period of time to comment at an early stage in the adoption process so that amendments to the proposed measures can still be made.¹¹⁶ Members are not obliged to disclose confidential information that could hamper the enforcement of their SPS measures or prejudice the legitimate interests of enterprises. The Secretariat has established guidelines on transparency, contained in the handbook *How to Apply the Transparency Provisions of the SPS Agreement*.¹¹⁷ These are particularly aimed at helping developing countries comply with their transparency obligations.

5.1.2 Notification Authority

Annex B.10 SPS

Members are further required to create the infrastructure necessary for the implementation of their notification obligations. Under Annex B.10, Members must designate a single central government authority as responsible for implementing the notification procedures in Annex B.5-8 on national level. The WTO Secretariat regularly updates and circulates lists of Members' Notification Authorities.¹¹⁸

5.1.3 Enquiry Points

Annex B.3 and 4 SPS

As part of the infrastructure necessary for transparency, the *SPS Agreement* obliges each Member to establish a national Enquiry Point. A Member's national Enquiry Point must provide answers to all reasonable questions from other Members as well as provide relevant documents regarding *inter alia*: any adopted or proposed SPS measures in its territory; the risk assessment basis for the measure; control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures. Requested copies of documents must be supplied to other Members at the same price as to nationals. The WTO Secretariat maintains an updated list of Enquiry Points which it circulates to Members.¹¹⁹

¹¹⁴ Appellate Body, *Japan - Agricultural Products II*, paras. 105-106.

¹¹⁵ Notifications received by the Secretariat are circulated to Members as part of the official document series G/SPS/N/*.

¹¹⁶ In urgent cases, Members may follow a shorter procedure under Annex B.6.

¹¹⁷ Published in November 2000, available at: http://www.wto.org/english/tratop_e/sps_e/spshand_e.pdf. The guidelines are non-binding and are not intended as a legal interpretation of the relevant provisions of the SPS Agreement. In addition, the Secretariat has drawn up and revised recommended procedures for the implementation of transparency obligations (G/SPS.7/Rev.2, dated 2 April, 2002).

¹¹⁸ These can be found in the G/SPS/NNA/* series of official WTO documents. By 11 March 2002, 115 of the then 144 WTO Members had established national Notification Authorities (G/SPS/GEN/27/Rev.9, dated 14 March 2002).

¹¹⁹ These can be found in the G/SPS/ENQ/* series of official WTO documents. By 11 March 2002, 122 of the then 144 WTO Members had established national Enquiry Points (*Ibid.*).

5.1.4 Explanation of Reasons

Article 5.8 SPS

A Member may request another Member to provide reasons for the latter's SPS measure where it is not based on international standards and it constrains or could potentially constrain the former Member's exports. The importing Member is then obliged to provide such reasons. This obligation is significant as it can assist a Member in establishing a *prima facie* case that another Member's SPS measure is not based on a risk assessment.

5.1.5 Importance of Notification for Developing Countries

Developing countries stand to gain particularly from the improvements in transparency achieved by the *SPS Agreement* as the cost and difficulty of obtaining information on their trading partners' SPS measures are thereby greatly reduced.

5.2 Control, Inspection and Approval Procedures

In order to ensure that their SPS measures are complied with, countries usually have control, inspection and approval procedures in place. If these procedures are lengthy, costly or complex, they may effectively restrict market access. The SPS Agreement addresses this problem in Article 8 and Annex C.

Article 8 SPS

According to Article 8, Members must comply with Annex C as well as the other provisions on the *SPS Agreement* in the operation of their control, inspection and approval procedures. This includes their national systems for approval of additives and establishment of tolerances for contaminants.

Annex C SPS

Annex C contains more detailed rules relating to control, inspection and approval procedures. These are mainly aimed at ensuring that the procedures are not more lengthy or burdensome than reasonable and necessary. In addition, exporting Members are obliged to facilitate the work of other Member's controlling authorities on their territories, where the SPS measure relates to control at the level of production.

5.3 SPS Committee

Article 12.1 SPS

A Committee on Sanitary and Phytosanitary Measures (SPS Committee) is established under Article 12.1. The SPS Committee consists of representatives¹²⁰ of all WTO Members¹²¹ and takes its decisions by consensus. The SPS Committee is serviced by the Agriculture and Commodities Division of the WTO Secretariat. The SPS Committee usually holds three meetings per year, and may convene informal meetings as necessary.

¹²⁰ Members may send representatives of their choice, and normally send officials from their food safety authorities or veterinary or plant health officials.

¹²¹ Observer status is granted to governments that have observer status in higher WTO bodies as well as representatives from certain international intergovernmental organizations with a mandate in this area (G/SPS/GEN/229, dated 23 February 2001).

The aim of the SPS Committee is to provide a regular forum for consultations and further the implementation of the *SPS Agreement* and the achievement of its aims, in particular the harmonization of standards.¹²²

5.3.1 Forum for Consultations

Article 12.2 SPS

Article 12.2 mandates the SPS Committee to encourage and facilitate consultations between Members on specific SPS issues. Coupled with the transparency obligations, this provision may go a long way towards allowing developing countries to solve SPS conflicts in a low-cost manner. Discussions on notified changes in SPS legislation take place, with concerns being raised by exporting Members and clarifications given by the Member imposing the measure.¹²³ This could lead to the revision of the notified measure or further bilateral consultations between the Members involved. In this way, disputes can be resolved without recourse to the expensive and time-consuming process of formal dispute settlement. In a recent study¹²⁴ it was shown that during SPS Committee meetings, around 120 SPS issues have been raised, almost half involving complaints by developing countries or transition economies.

5.3.2 Role Regarding the Process of International Harmonization

Article 12.2-6 SPS

The SPS Committee is given various tasks regarding the process of international harmonisation of SPS standards. It must encourage the use of international standards, guidelines and recommendations by all Members, and maintain close contact with the three main international standard-setting organizations. Further, the SPS Committee must develop a procedure to monitor the process of international harmonization and the use of international standards. A provisional procedure was established,¹²⁵ in terms of which the SPS Committee draws up annual reports based on information and comments from Members and international standard-setting organizations regarding the use of existing international standards, the need for new international standards and work on the adoption of such standards. Further, Article 12.5 allows the SPS Committee to use information gathered by the international organizations, to avoid duplication. Finally, the Committee may, in terms of Article 12.6, invite the international organizations to examine specific matters with regard to a particular standard, guideline or recommendation, including the basis for explanations of non-use of the standard.

¹²² In terms of this power, the SPS Committee adopted the Equivalence Decision in 2001, in order to facilitate the implementation of Article 4 of the SPS Agreement. This decision is further discussed in section 4 above.

¹²³ The Secretariat provides a summary of all specific trade-related concerns raised in the SPS Committee, together with an indication of the resolution of the issue, if notified (G/SPS/GEN/204/Rev.1, dated 5 March 2001).

¹²⁴ Micheal Friis Jensen, *Reviewing the SPS Agreement: A Developing Country Perspective Working Paper 02.3*, Centre for Development Research: Copenhagen at 18, table 1 (2002).

¹²⁵ G/SPS/11, dated 22 October 1997. This procedure was extended twice.

5.3.3 Periodic Review of the Operation and Implementation of the SPS Agreement

Article 12.7 SPS

The SPS Committee was obliged by Article 12.7 to review the operation and implementation of the *SPS Agreement* three years after its entry into force, and thereafter as the need arises. Where appropriate, the SPS Committee may make proposals to the Council for Trade in Goods regarding amendments to the *SPS Agreement*. The SPS Committee established a procedure for this review¹²⁶ and the first review was conducted in 1998, resulting in a report of the SPS Committee.¹²⁷ However, no amendments were proposed. The SPS Committee noted that the review had not been comprehensive and recognized that Members could raise any issue for the consideration of the Committee at any time.

Doha Decision on Implementation

In the Ministerial *Decision on Implementation* adopted in Doha, the SPS Committee is instructed to review the operation and implementation of the *SPS Agreement* at least once every four years.

5.4 Dispute Settlement

In order to enforce their rights under the SPS Agreement, Members can have recourse to the dispute settlement system of the WTO, as embodied in the Dispute Settlement Understanding (DSU).¹²⁸ The rules and procedures set out in the DSU apply fully and unconditionally to disputes arising under the SPS Agreement.

To date, there have been 21 complaints under the SPS Agreement regarding 18 separate issues. Three disputes have resulted in panel and Appellate Body reports¹²⁹ and one dispute is currently before a panel.¹³⁰ Developing countries¹³¹ have been involved in seven disputes, in four cases as complainant¹³² and in six as defendant.¹³³

Three issues regarding the settlement of disputes arising under the SPS Agreement deserve particular attention: the burden of proof; the standard of review; and the use of scientific experts and expert review groups.

5.4.1 Burden of Proof

The question of which party bears the evidentiary burden is particularly

¹²⁶ G/SPS/10, dated 21 October 1997.

¹²⁷ G/SPS/12, dated 11 March 1999.

¹²⁸ The dispute settlement system is discussed in detail in Modules 3.1 to 3.4. Thus here attention will only be given to specific aspects applicable to SPS disputes.

¹²⁹ These are EC – Hormones, Australia – Salmon and Japan – Agricultural Products. The findings in these cases have been discussed above where relevant.

¹³⁰ A panel was established on 3 June 2002 to address the United States complaint against Japan's restrictions on apples due to fire blight (WT/DS245).

¹³¹ Developing countries here is interpreted broadly to include economies in transition.

¹³² WT/DS134, WT/DS205, WT/DS237 and WT/DS256.

¹³³ WT/DS96, WT/DS133, WT/DS203, WT/DS205, WT/DS237 and WT/DS256.

significant in the case of disputes on health measures due to the degree of scientific uncertainty that exists in this area. In *EC - Hormones* the Appellate Body emphasised the importance of this issue, in the light of the “multiple and complex issues of fact” that may arise under the *SPS Agreement*.¹³⁴ It held that the normal rule with respect to the burden of proof applies, namely that the party asserting a fact must establish a *prima facie* case that it is true and then the evidentiary burden shifts to the other party who must rebut the presumption or lose the case.¹³⁵

In *Japan - Agricultural Products*, the United States claimed that requiring the complainant to prove that there is insufficient scientific evidence for a measure under the *SPS Agreement* amounts to requiring it to prove a negative, placing an impossible burden on the complainant.¹³⁶ The Appellate Body rejected this argument, finding that the United States was not being required to prove a negative, but merely to raise a presumption that there were no relevant studies or reports. According to the Appellate Body, the United States could have requested Japan, under Article 5.8, to provide an “explanation of the reasons” for its measure as it related to the products at issue. The failure of Japan to do so would have amounted to a strong indication that such studies or reports did not exist. Further, the United States could have questioned the Panel’s experts or submitted an opinion of its own experts on the question whether such reports exist.

Aside from the issue of the burden of proof under the *SPS Agreement* generally, the harmonization provision contained in Article 3 of this Agreement presents interesting specific burden of proof issues. The Appellate Body in *EC - Hormones* rejected the panel’s finding that Article 3.3 embodies an exception to the general rule contained in Article 3.1 and thus that the burden of proof shifts to the defending Member to show that its measure complies with Article 3.3. Instead, the Appellate Body held that Article 3.1 of the *SPS Agreement* merely excludes from its scope situations falling under Article 3.3. Article 3.3 contains an autonomous option available to Members and it is for the challenging Member to prove that the conditions laid down in this article for SPS measures not based on international standards are not met.¹³⁷

5.4.2 Standard of Review

Article 11 DSU

The issue of the appropriate standard of review is an important one, as it raises the question of the extent to which panels are entitled to interfere in Members’ regulatory determinations. In *EC - Hormones*¹³⁸ the question of the appropriate standard of review was first dealt with. The Appellate Body rejected the extension of the deferential standard of review set in the *Anti - Dumping Agreement* to the *SPS Agreement*, holding that this standard is textually specific

¹³⁴ Appellate Body Report, *EC - Hormones*, para. 97.

¹³⁵ Appellate Body Report, *EC - Hormones*, paras 102-105.

¹³⁶ Appellate Body Report, *Japan - Agricultural Products*, para. 38.

¹³⁷ Appellate Body Report, *EC - Hormones*, para. 104.

¹³⁸ Appellate Body Report, *EC - Hormones*, para. 133.

to the former Agreement and there is no evidence of an intention to adopt it in the latter Agreement.

The Appellate Body found that although the *SPS Agreement* is silent on the issue of the standard of review, the DSU articulates this standard both for the determination of the facts and the legal characterization of these facts, in Article 11.¹³⁹ The standard of review established by this Article is neither total deference nor *de novo* review, but rather the objective assessment of the facts (with respect to fact-finding) and an objective assessment of the matter, including the applicability of and conformity with the relevant covered agreements (with respect to legal issues).¹⁴⁰

The Appellate Body held that a claim that the panel failed to conduct an objective assessment of the facts requires proof that there has been deliberate disregard of or refusal to consider submitted evidence or wilful distortion or misrepresentation of the evidence. These do not indicate a mere error of judgement but imply an egregious error, which calls into question the good faith of the panel.¹⁴¹

5.4.3 Scientific Experts and Expert Review Groups

Article 11.2 SPS

An attempt to deal with the problems inherent to the evaluation of scientific evidence is reflected generally in Article 13 of the DSU and for health matters more specifically in Article 11.2 of the *SPS Agreement*. Article 13.1 of the DSU authorizes panels to seek information and technical advice from any individual or body. Article 13.2 allows panels to seek information from any source and to consult experts or request advisory reports from expert review groups. Article 11.2 of the *SPS Agreement* states that in disputes under that Agreement, involving scientific or technical issues, a panel should consult experts chosen by it in consultation with the parties. For this purpose, a panel may set up advisory technical experts groups or consult relevant international organizations.

It is within a panel's discretion¹⁴² whether to consult individual experts or to establish an expert review group.¹⁴³ All panels dealing with issues under the *SPS Agreement* thus far have consulted individual experts.

5.5 Test Your Understanding

1. Set out the main transparency obligations under the SPS Agreement and discuss their importance for developing countries.

¹³⁹ Appellate Body Report, *EC –Hormones*, para. 116.

¹⁴⁰ Appellate Body Report, *EC –Hormones*, para. 117.

¹⁴¹ Appellate Body Report, *EC –Hormones*, para. 133.

¹⁴² Appellate Body Report, *EC –Hormones*, para. 147.

¹⁴³ The rules and procedures applying to expert review groups are set out in Appendix 4 of the DSU.

- 2. What are the main functions of the SPS Committee? Which of these would you consider most important for developing countries and why?**
- 3. Discuss the standard of review that panels must apply when examining claims under the SPS Agreement.**

6. SPECIAL PROVISIONS FOR DEVELOPING COUNTRIES

On completion of this section the reader will be able:

- to identify those rules in the *SPS Agreement* that take account of the special position of developing countries.
- to assess in how far the *SPS Agreement* provides flexibility for developing countries in the implementation of their commitments and encourages developed countries to take account of developing country constraints.

6.1 Recognition of Constraints of Developing Countries

The general disciplines of the *SPS Agreement* apply equally to developed and developing countries. However, the *SPS Agreement* does reflect a recognition of the financial and technical resource constraints that developing countries face.¹⁴⁴ For this reason, special provisions exist that take into account the special position of developing countries. These provisions relate to the provision of technical assistance to developing countries as well as to special and differential treatment in favour of developing countries. In addition, it should not be forgotten that some of the disciplines in the *SPS Agreement* discussed above contain elements of flexibility that can be used to the benefit of developing countries.¹⁴⁵

6.2 Technical Assistance

The technical assistance needs of developing countries relate not only to improving their understanding of the rules applicable under the *SPS Agreement* but also to the acquisition of technical and scientific capacity to meet their obligations and enforce their rights under the *SPS Agreement*. Thus technical assistance is a broad term, encompassing:

- the provision of information to enhance Member's understanding of their rights and obligations under the *SPS Agreement*;
- the provision of practical and detailed training on the operation of the *SPS Agreement*; the provision of "soft" infrastructure (training and formation of technical and scientific personnel and the development of national regulatory frameworks); and
- "hard" infrastructure (laboratories, equipment, veterinary services, establishment of disease free areas).¹⁴⁶

¹⁴⁴ This recognition is first mentioned in the 7th preambular paragraph of the *SPS Agreement*.

¹⁴⁵ For example, Article 5.1 requires a risk assessment "as appropriate to the circumstances"; Article 5.6 allows technical and economic feasibility to be taken into account in the choice of an *SPS* measure; Annex B para. 8 exempts developing countries from the requirement to provide copies or summaries of documents covered by a notification.

¹⁴⁶ This typology was drawn up by the Secretariat (G/SPS/GEN/206, dated 18 October 2000).

The provision of technical assistance to developing countries involves several actors, including other WTO Members, the WTO Secretariat as well as other international organizations such as the FAO (including Codex and the IPPC), the WHO, the OIE and the World Bank. It should be noted that the active participation and contribution of developing countries in this process is essential in order to ensure that the provision of technical assistance is demand-driven.

Article 9 SPS

Under Article 9.1, Members *agree to facilitate* the provision of technical assistance to other Members, especially developing countries, either bilaterally or through international organizations. This assistance may take various forms, including advice, credits, grants and donations and may be in the areas of processing technologies or research and infrastructure, including the creation of national regulatory bodies. This form of assistance may also aim at helping developing countries adjust to and comply with SPS measures on their export markets.

Article 9.2 refers specifically to the case where an importing Member's SPS requirements necessitate substantial investments by a developing country exporting Member in order to comply with these SPS requirements. In such a case, the importing Member must consider providing technical assistance that will enable the developing country Member to maintain and expand its market access opportunities for that product. However, there is no obligation to actually provide such technical assistance.

Technical assistance is a standing item on the agenda of SPS Committee meetings, where Members are encouraged to identify specific technical assistance needs and report on technical assistance activities. The SPS Committee¹⁴⁷ has undertaken a survey of technical assistance needs and activities by means of questionnaires¹⁴⁸ and drawn up a technical assistance typology.¹⁴⁹ In addition, informal discussions on technical assistance and cooperation have been held in the SPS Committee.¹⁵⁰ Further, high-level as well as technical meetings have been held between the WTO and other international organizations to coordinate the provision of technical assistance.¹⁵¹

Doha Decision on Implementation

The *Decision on Implementation* taken at the Ministerial Conference in Doha urges the WTO Director-General to continue cooperative efforts with the international standard-setting organizations to facilitate the provision of technical and financial assistance to ensure the effective participation of least-developed countries. In addition, Members are urged to provide technical and

¹⁴⁷ A compilation of all documents on this issue submitted to and drafted by the SPS Committee was circulated to all Members (G/SPS/GEN/332, dated 24 June 2002).

¹⁴⁸ In July 1999 a questionnaire was circulated to Members to gather information on technical assistance requested, received or provided under the SPS Agreement (G/SPS/W/101, dated 23 July 1999) but few developing countries replied. In October 2001 a second questionnaire was circulated regarding technical assistance needs (G/SPS/W/113, dated 15 October 2001) to which 24 Members have responded to date (see addenda to G/SPS/GEN/295, dated 6 February 2002).

¹⁴⁹ G/SPS/GEN/206, dated 18 October 2000.

¹⁵⁰ The first meeting was held in July 2002 (G/SPS/GEN/267, dated 16 July 2001) and the second in March 2002 (no unrestricted report available yet).

¹⁵¹ See reports: WT/GC/42, dated 11 December 2000; WT/GC/46/Rev.1, dated 16 July 2001; WT/GC/54, dated 7 November 2001; WT/GC/45, dated 7 March 2001.

financial assistance to least-developed countries to enable them to respond to SPS measures which may negatively affect their trade as well as to ensure that technical assistance is provided to these countries in response to the special problems they face in implementing the *SPS Agreement*.¹⁵²

**Standards and Trade
Development Facility**

The World Bank and the WTO established a new fund, on 27 September 2002, to provide funding to developing countries to assist them to meet SPS standards. The World Bank has pledged US\$300,000 and the WTO will contribute from the Doha Development Trust Fund. The fund will be administered by the WTO. The FAO, WHO and OIE are expected to join in this initiative.¹⁵³

6.3 Special and Differential Treatment

Special and differential treatment under the *SPS Agreement* is aimed at ensuring that the special constraints faced by developing country Members are taken into account in the implementation of certain provisions of the *SPS Agreement*. This may refer to implementation of provisions in a manner favourable to developing countries by other Members, flexibility in the obligations in favour of developing countries, or actions by the SPS Committee or Secretariat to assist developing countries.

6.3.1 Preparation and Application of SPS Measures

Article 10.1 SPS

Article 10.1 obliges Members to *take account of* the special needs of developing country Members, and in particular least-developed country Members when preparing and applying SPS measures. However, beyond requiring that these needs be considered in the regulatory process, there is *no obligation* to adapt the SPS measures or their application in accordance with developing country needs.

6.3.2 Phased-in Introduction of Measures

Article 10.2 SPS

Article 10.2 encourages Members, without obliging them, to allow longer time frames for compliance with new SPS measures for developing country Members, where the appropriate level of protection of the importing Member allows scope for this. This is aimed at allowing developing countries to maintain their export opportunities while adjusting to the new measures.

**Doha Decision on
Implementation**

The *Decision on Implementation* adopted at the Doha Ministerial Conference sets the longer time frame for compliance under Article 10.2 at “normally a period of not less than six months” where there is scope for phased introduction of the new measure. Where such phased introduction is not possible, if a Member identifies specific problems it faces with regard to the new measure, the importing Member must enter into consultations with a view to reaching a

¹⁵² WT/MIN(01)/17, dated 14 November 2001.

¹⁵³ See WTO Press Release 314 “World Bank grant kicks off Bank-WTO assistance on standards” dated 27 September 2002.

mutually satisfactory solution, while continuing to achieve the importing Member's appropriate level of protection.¹⁵⁴

6.3.3 Reasonable Adaptation Period

Annex B.2 SPS

Members are obliged,¹⁵⁵ under paragraph 2 of Annex B, to allow a reasonable period between the publication of a SPS measure and its entry into force for exporting Members (especially developing countries) to adapt to the new measure.

Doha Decision on Implementation

The *Decision on Implementation* adopted at the Doha Ministerial Conference sets the reasonable adaptation period at "normally a period of not less than six months," but notes that the particular circumstances of the measure and the actions needed for its implementation must be considered. In addition, it clarifies that the entry into force of SPS measures that liberalize trade should not be unnecessarily delayed. This takes into account the fact that some new SPS measures may set lower or easier requirements than existing ones.¹⁵⁶

6.3.4 Time-Limited Exemptions

Article 10.3

Article 10.3 allows the SPS Committee to grant developing countries, upon request, specified, time-limited exemptions to all or some of their obligations under the *SPS Agreement*. This is done with the aim of enabling developing countries to comply with their obligations, and takes account of their financial, trade and development needs. No developing country has requested such an exemption to date.

6.3.5 Facilitation of Participation in International Organizations

Article 10.4 SPS

Article 10.4 provides that Members should encourage and facilitate the active participation of developing countries in the relevant international organizations. This is clearly a reference to the international standard-setting organizations, namely the CAC, IPPC and OIE. Article 10.4 is purely hortatory and contains no binding obligation.

6.3.6 Special Provisions on Notification

Annex B.8 and 9 SPS

Under the transparency provisions of Annex B, developing countries are exempted from the obligation to provide copies of the documents on which a notification is based in one of the official languages of the WTO. In addition, the Secretariat is obliged to draw the attention of developing countries to any notifications relating to products of interest to them. This is done by means of the circulation of monthly lists of notifications to all Members.

¹⁵⁴ *Ibid.*, para. 3.1.

¹⁵⁵ *Except in cases of urgency.*

¹⁵⁶ WT/MIN(01)/17, dated 14 November 2001.

6.3.7 *Transitional Periods*

Article 14 SPS

Article 14 of the *SPS Agreement* made provision for delayed implementation of the obligations under the Agreement for developing and least-developed country Members. Least-developed Members were granted a five-year period, from the entry into force of the *WTO Agreement*, for delayed application of all their obligations. Other developing Members were given a two-year grace period, where lack of technical expertise, infrastructure or resources prevented immediate application of their obligations. However, this possibility did not extend to their transparency and information obligations. The period for delayed application expired in 2000 for least-developed Members and 1997 for other developing Members.

6.4 Test Your Understanding

- 1. Do developing countries have a right to receive technical assistance in order to comply with the SPS measures of their trading partners?**
- 2. What initiatives have been taken by the SPS Committee to facilitate the implementation of the provisions on technical assistance?**
- 3. List the ways in which special and differential treatment for developing countries is provided for in the *SPS Agreement* and mention any improvements agreed upon in the Doha Ministerial Conference.**

7. CASE STUDIES

1. The Republic of Agricola, a developing country WTO Member, relies primarily on its exports of mangoes and tomatoes for its foreign revenue earnings. Its main export market is Industria, a developed country Member of the WTO. In recent years, exporters from Agricola have faced increasing obstacles to the entry of their products into the market of Industria, due to concerns that these products do not meet the SPS standards deemed appropriate by the government of Industria. In particular, Industria has enacted a law requiring fumigation treatment for all mangoes from Agricola, due to its detection of the presence of black borer beetles (a pest of quarantine significance for Industria) in a shipment of mangoes from Agricola five years ago. In addition, due to its zero-risk policy with respect to carcinogens, Industria has provisionally set a no-residue level for the presence of Xenogen, an herbicide that is a suspected carcinogen, on imports of vegetables. Xenogen is a cheap and effective herbicide and in common use among Agricolan tomato farmers.

In a meeting with the Agricolan Department of Agriculture, the farmers' union of the Republic of Agricola raised several concerns regarding these measures, viewing them as a disguised form of protection of the agricultural industry of Industria rather than legitimate SPS measures. Firstly, the farmers' union points out that black borer beetles are only to be found in the humid eastern province of Agricola, since this species of beetle does not thrive in the drier western provinces. Secondly, it notes that new phytosanitary legislation in Agricola requires mangoes to be subject to refrigeration treatment in order to destroy pests. It claims that this treatment as effective as fumigation for the extermination of black borer beetles and is less detrimental to the shelf life of the fruit. However, despite requests from Agricola, Industria has been unwilling to recognise refrigeration treatment as equivalent to fumigation. Thirdly, the farmers' union points out that the carcinogenic potential of Xenogen has never been conclusively proven. Lastly, the farmers note that no reasonable period of time was allowed for them to adapt to the new requirement of Industria with regard to Xenogen. As a result, they stand to lose their market share while they switch to a new herbicide. In addition, the added costs of the new herbicide make it impossible for many smaller farmers to make this change and remain competitive.

You are the representative of the Republic of Agricola at the SPS Committee of the WTO. Your government approaches you for advice on how it should proceed in this matter. It asks you to write an opinion on this issue. In particular, it asks you to address the following points:

- (a) Are there mechanisms available to the government of Agricola to resolve this dispute without resorting to dispute settlement?
- (b) In case Agricola decides to resort to dispute settlement, should it challenge Industria's measures under the GATT 1994, the *SPS Agreement* or the *TBT Agreement* or a combination of these?

- (c) In case of a challenge under the *SPS Agreement*, which party would bear the burden of proof? If Agricola bears the burden of proof, is there any mechanism in place to assist it in obtaining information from Industria regarding its measures?
 - (d) Are there provisions in the *SPS Agreement* which Agricola, as a developing country, could rely upon to complain that Industria did not take its special needs into account when enacting and implementing these measures? If so, what are the chances of success in challenging measures under such provisions?
 - (e) Can Agricola challenge Industria's refusal to recognize the existence pest-free areas in Agricola and to adapt its requirements accordingly or to recognize Agricola's phytosanitary measures as equivalent to its own? If so, what would Agricola have to prove?
 - (f) Can Agricola challenge the zero-risk level of protection adopted by Industria with regard to carcinogens or its zero-residue level with regard to Xenogen?
 - (g) Does the *SPS Agreement* make it possible for Agricola to challenge Industria's measure with regard to Xenogen on the grounds that there is insufficient scientific evidence of a risk? Are there any special rules applicable to "provisional" measures?
2. As a small, island developing country, Agricola is a net importer of food, which it buys from the revenue it earns from its mango and tomato exports. Traditionally, Agricolan people eat large quantities of beans, which Agricola imports from neighbouring countries, especially Bundastan (also a developing country WTO Member). As a result of the importance of beans in the national diet, food safety legislation has been in place in Agricola for the last 15 years, setting a maximum residue level for Fitolene a certain chemical commonly used as a fertiliser in bean production, including in Bundastan. This legislation was enacted in response to a sudden increase in epilepsy cases in a region where fertiliser with Fitolene was introduced. There are some indications that there is a link between the Fitolene and epilepsy. The Agricolan government is trying to establish whether this link can be shown scientifically, but due to the complexity of epilepsy and resource constraints this is taking a long time. In recent years, Fitolene has come to the attention of the Codex Alimentarius Commission. In 2001, the Codex Alimentarius Commission decided not to adopt a maximum residue level for Fitolene, based on the conclusion of the Joint FAO/WHO Meeting on Pesticide Residues that scientific studies show Fitolene to be safe, if used in accordance with good farming practice. Due to financial and resource constraints, Agricola was not able to participate in the discussions which led to the adoption of this decision in the Codex. It has come to its attention that the same is true for several small developing countries. In addition, a small group of Nordic scientists have recently published a peer-reviewed study which they believe shows that Fitolene, when ingested in large amounts, can have adverse health effects.

In order to balance the diet of its citizens, Agricola also imports rice and maize. Recently there has been an outbreak of blue fungus on maize crops in

neighbouring Bundastan, which is a disease that can spread to mangoes and cause great economic harm to Agricola's export crops. Agricola has therefore banned the importation of maize from Bundastan. A recent study by the United Nations Food and Agricultural Organization has shown that yellow rot, often found in rice, is a disease which can spread just as easily to mango trees, yet Agricola has no measures in place to restrict the importation of rice with yellow rot. In the last meeting of the SPS Committee, Bundastan has raised its concerns regarding Agricola's measures with regard to its bean and maize exports. It has also tabled a detailed document in which it sets out more specifically its complaints regarding the Agricolan measures. You are the representative of Agricola on the SPS Committee. You take note of Bundastan's concerns and undertake to respond to them at the next meeting of the SPS Committee, both orally and by means of a written document in the hope of avoiding a dispute settlement proceeding. You are now drafting this response. You must address the specific claims raised by Bundastan, which are the following:

- (a) Agricola's maximum residue level for Fitolene is not based on the international standard set by Codex, which is "no maximum residue level" for Fitolene. Thus the requirements of Article 3.1 of the *SPS Agreement* are not complied with and Agricola must prove that its measure falls within the exception provided for under Article 3.3.
- (b) Agricola's maximum residue level for Fitolene does not comply with Article 3.3 as it is not based on a risk assessment in terms of Article 5.1.
- (c) Agricola's maximum residue level for Fitolene is not a provisional measure under Article 5.7 as it has been in place for 15 years.
- (d) Agricola is not consistent in the application of its appropriate level of protection and makes arbitrarily distinctions in the level of protection it deems appropriate in different situations, in violation of Article 5.5, when it bans maize from Bundastan due to risks from blue fungus while allowing free importation of rice bearing equally significant risks from yellow rot.

Your government would like you to include the following arguments in your response, where appropriate, in addition to your own arguments. You should identify which of these arguments are valid under the *SPS Agreement* and only refer to those.

- (a) As Agricola's maximum residue level was already in place at the time of coming into force of the *SPS Agreement*, it does not have to comply with its requirements.
- (b) Since Agricola and several other developing countries did not participate in the Codex meetings setting the standard for Fitolene, this is not an "international standard" for purposes of the *SPS Agreement* (or Agricola and these other developing countries are not bound by the international standard).
- (c) The Codex standard is not appropriate for Agricola due to the large quantities of beans consumed by its citizens. The international standard therefore does not meet the level of protection set by Agricola.

- (d) Agricola's status as a developing country should be taken into account in determining whether a risk assessment "as appropriate to the circumstances" exists.
- (e) Agricola's maximum residue level for Fitolene is based on the risk assessment conducted by the Nordic scientists.
- (f) The distinction in levels of protection deemed appropriate for risks from blue fungus and from yellow rot is not arbitrary but is based on the fact that yellow rot is easy to cure by simply spraying the mango trees with salt water, whereas the eradication of blue fungus is difficult and costly.

8. FURTHER READING

8.1 Articles

- **Charnovitz, S.** 2000, “Improving the Agreement on Sanitary and Phytosanitary Standards.” *Trade, Environment, and the Millennium*, edited by G.P. Sampson and W.B. Chambers, 172-193. New York: United Nations University Press.
- **Jensen, M.F.** 2002, “Reviewing the SPS Agreement: A Developing Country Perspective” Working Paper 02.3 Centre for Development Research: Copenhagen.
- **Otsuki, T.**, Wilson, J.S, and Sewadeh, M., 2001, “Measuring the Effect of Food Safety Standards on African Exports to Europe.” *The Economics of Quarantine and the SPS Agreement*, edited by K. Anderson, C. McRae and D. Wilson. Adelaide: Centre for International Economic Studies.
- **Pauwelyn, J.** 1999, “The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes: EC - Hormones, Australia - Salmon and Japan - Varietals.” *Journal of International Economic Law*: 641-664.
- **Quick, R., and Blüthner, A.** 1999, “Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO *Hormones Case*.” *Journal of International Economic Law* 2, no. 4: 603-639.
- **Roberts, D., Orden, D., and Josling, T.** 1999, “WTO Disciplines on Sanitary and Phytosanitary Barriers to Agricultural Trade: Progress, Prospects and, Implications for Developing Countries.” Paper presented at the *Conference on Agriculture and the New Trade Agenda in the WTO Negotiations*, Geneva, 1-2 October.
- **Victor, D.G.** 2000, “The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years.” *Journal of International Law and Politics* 32, no. 4: 865-938.
- **Walker, V.R.** 1998, “Keeping the WTO from Becoming the ‘World Trans-Science Organization’: Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute.” *Cornell International Law Journal* 31: 251-320.
- **Zarrilli, S.**, 2001, “United Nations Conference on Trade and Development: International Trade in Genetically Modified Organisms and Multilateral Negotiations - a New Dilemma for Developing Countries.” *Business Law International*, no. 3: 330-369.

8.2 Appellate Body Reports

- Appellate Body Report, *Australia – Measures Affecting the Importation of Salmon* (“*Australia - Salmon*”), WT/DS18/AB/R, adopted 6 November 1998.
- Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)* (“*EC - Hormones*”), WT/DS26/AB/R; WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135.
- Appellate Body Report, *Japan - Measures Affecting Agricultural Products* (“*Japan - Agricultural Products II*”), WT/DS76/AB/R, adopted 19 March 1999.

8.3 Panel Reports

- Panel Report, *Australia – Measures Affecting Importation of Salmon, Complaint by Canada* (“*Australia - Salmon*”), WT/DS18/R, adopted 6 November 1998 as modified by the Appellate Body Report, WT/DS18/AB/R.
- Compliance Panel Report, *Australia – Measures Affecting Importation of Salmon - Recourse to Article 21.5 of the DSU by Canada* (“*Australia – Salmon*”), WT/DS18/RW, adopted 20 March 2000.
- Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, complaint by the United States (“*EC - Hormones (US)*”), WT/DS26/R/USA, adopted 13 February 1998 as modified by the Appellate Body Report, WT/DS26/AB/R; WT/DS48/AB/R, DSR 1998:III, 699.
- Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, complaint by Canada (“*EC - Hormones (Canada)*”), WT/DS48/R/CAN, adopted 13 February 1998 as modified by the Appellate Body Report, WT/DS26/AB/R; WT/DS48/AB/R, DSR 1998:II, 235.
- Panel Report, *Japan - Measures Affecting Agricultural Products*, complaint by the United States (“*Japan - Agricultural Products II*”), WT/DS76/R, adopted 19 March 1999 as modified by the Appellate Body Report, WT/DS76/AB/R.

8.4 Documents and Information

- Official WTO documents can be obtained by searching on the WTO’s online document database, available at: <http://docsonline.wto.org/>
- Official documents of the Codex Alimentarius Commission can be obtained by searching on the official website of the Codex Alimentarius Commission, available at: <http://www.codexalimentarius.net/>
- Official documents of the International Plant Protection Convention can be obtained by searching on the official website of the International Plant Protection Convention, available at: <http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/PQ/Default.htm>

- Official documents of the International Office of Epizootics can be obtained by searching on the official website of the International Office of Epizootics, available at: ***<http://www.oie.int/>***